A NON-CONFORMANCE CLASSIFICATION AND RAPID CONTROL METHOD FOR IMPROVED PRODUCT VALIDATION

by

Roslan Jamaludin

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dedicated to

Nor'ain
Muzammil, Ateeqa, Hanif
our parents
Uncle Ahmed, Muslina

ABSTRACT

Product quality is a topic of significant industrial importance and has been the subject of ongoing research over many years. However, the study of non-conformance reduction in the pre-production stage of product development has received only limited attention. Although products undergo chronological and rigid assessments, there are still non-conformances which are detected late in development stages particularly in pre-production. Furthermore, these non-conformances are problematic when rectification cannot be found rapidly and these problems are then carried over into production.

The research, which is based on consumer electronic product, addresses product non-conformance in the pre-production. The work reported in this thesis focuses on the identification and control of non-conformances to facilitate improved product validation and aids the pre-production team in product assessment and decision making. The research has adopted a holistic approach which is believed to be essential in order to provide a comprehensive and rapid rectification to non-conformances. Major emphasis has been placed on analysing the manifestation of mistakes which results in non-conformances and their relationship with the characteristics of the product under validation.

New approaches of non-conformance classification and rapid control method have been defined based on four interconnected aspects: manifestation of mistakes, product characteristics, non-conformance consequences and non-conformance solutions. A validation workbook has been formulated outlining the concepts and deployment of the new approaches for improved product validation process. These have been evaluated and are perceived to be feasible and applicable in pre-production. The research contributes to the understanding of the product quality deficiency as the consequence of mistakes. It has been shown that quality deficiency can be minimised by addressing non-conformances during product validation in pre-production.

Key words: Quality, Product Design and Development, Manufacturing, Pre-production, Validation, Product Non-conformance, Mistakes

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CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

In the Product Development Process (PDP), products which are found to be outside specification are said to be non-conformant and can be a major cost to manufacturing industry. Non-conformances contribute to unreliable product quality, which shows up, for example, as functional failure (Almgren, 2000) and poor appearance. Whilst most non-conformances are manifested and identified at the later stages of product development, they often escape into production and into the hands of users (Booker, 2003). The later non-conformances identified, especially late in development, the higher the cost incurred to rectify a product, for example (Milne, 1994, cited in de Castro and Fernandes, 2004) by,

- direct repair or replacement cost,
- loss of revenue while unavailable,
- costs of finding replacement services/items during unavailability,
- costs of consequential damage,
- consequential costs to avoid failure on similar items, and
- other implications such as safety, loss of confidence, image, and trade.

There has been a lack of empirical studies on (1) the understanding of non-conformances, and (2) the methodological principles of how to improve product validation in pre-production (Almgren, 2000; Nagasaka, 2000; Liu and Cheraghi, 2004). Most research describes non-conformances either from a broad or narrow aspect. The broad aspect describes non-conformances in the context of the overall product development process with cost as the main discussion, while the narrow aspect presents mathematical and statistical analysis in problem solving on a specific non-conformance

issue. This research, however, centred in exploring and investigating product non-conformances within pre-production.

In the pre-production phase of Product Development, non-conformances are identified during product validation. Currently, companies describe non-conformances identified during product validation in a distinctive method. For example by colour coding, alphabetical grading, or the simple no/no-go; the decision on how to describe non-conformances depends on the perception and experience of the senior staff in the company. This results in inconsistency in dealing with non-conformances when different people and circumstances exist. The result of validation will decide if a product can proceed to full production. This research is interested in improving validation practice to address non-conformances and to conduct an effective product validation in the development of consumer electronic product.

1.2 PROBLEM STATEMENT AND RESEARCH QUESTIONS

Product development process in typical consumer electronic product industry is constrained by design push and production pull where current market and technology forces companies to design and produce products speedily against extreme time pressure. As a consequence, non-conformances inadvertently occur throughout product development only to be identified in later stages of design, in pre-production, and during and after production.

In pre-production, there are two problems related to these non-conformances. On the one hand, the causes of non-conformances are not well understood and therefore the validation process tends to react to specific occurrence of non-conformances. Having a better understanding of potential areas of non-conformances would allow the validation process to be planned more effectively, thereby minimising the consequences of non-conformances to downstream activities. On the other hand, current validation practices are limited in resolving non-conformance problems. Methods of identification and controlling non-conformances are either too complicated, time consuming or too simplistic.

Consequently, as described earlier, non-conformances recur in production and when in use by customers. There is a need for a new understanding of non-conformances taking into account, for example, characteristics, types, causes, consequences, solutions, and preventions; and followed by improved product validation practices to identify and control non-conformances. Therefore, the research reported in this thesis intends to answer the following research questions:

1. Can a holistic classification of non-conformances be developed which provides greater clarity of likely problems and hence improve the validation process?
2. Can an effective methodology be developed to rapidly control product non-conformance in pre-production?

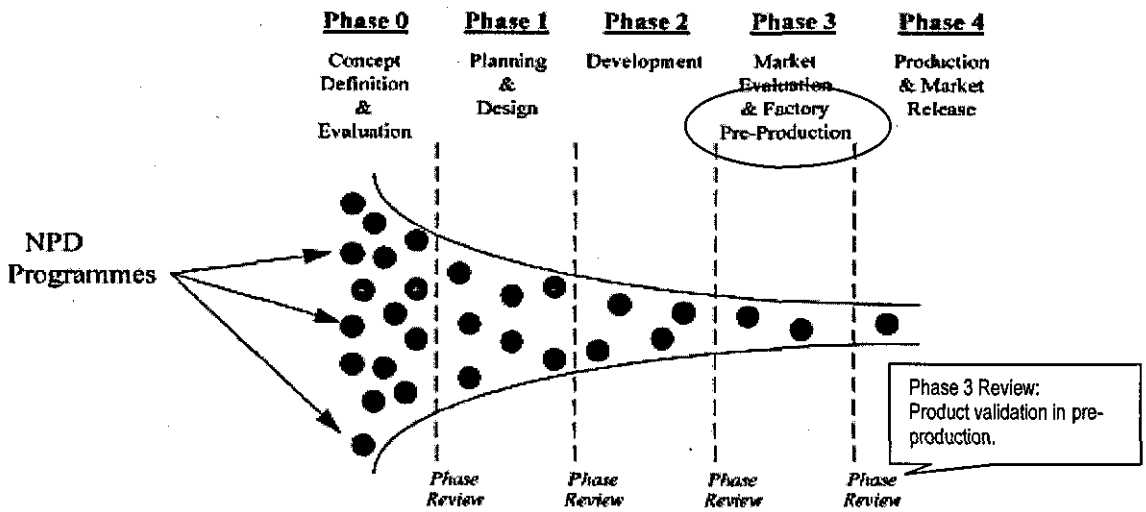
The study presented in this thesis contributes to the domain of product quality, and process improvement within the Product Development Process. The focus of the research is on product non-conformance and validation in pre-production, with the ultimate aim of improving methods for delivering high quality products.

1.3 RESEARCH AIM AND OBJECTIVES

This research is aimed at exploring and investigating product non-conformance and improved validation practices through identification and control of non-conformances in pre-production within the consumer electronic product industry. To achieve this aim, the following objectives have been pursued:

1. to review current research and industry practices related to product non-conformance and validation in pre-production.
2. to understand the critical aspects in the identification and control of non-conformances.
3. to formulate new approaches to identify and control non-conformances during product validation.
4. to generate a product validation process workbook based on the new approaches.
5. to evaluate the applicability of the new approaches .

The focus of this thesis is in *Phase 3 Review: Factory Pre-production,* as shown in Figure 1-1. This figure is based on the *Funnel Diagram* (Anthony, 1992, cited in Shepherd and Ahmed, 2000) which depicts the chronology of Product Development Phases and Reviews within Product Development Process, representing five phases (Phase 0 to Phase 4) of the typical New Product Development (NPD) programme. As a new product evolves and progresses to subsequent phases, appropriate reviews are carried out according to each phase's requirement. The review in Phase 3 is called *Product Validation.*



Note: NPD = New Product Development.
Source: Shepherd and Ahmed (2000).

Figure 1-1 Product Development Phases and Reviews

1.4 RESEARCH METHOD

This research intends to identify and control non-conformances during the product validation process. From the literature review and an industrial case study, the research gap has been identified. This leads to the formulation and deployment of research ideas in addressing product non-conformance in pre-production, and followed by industrial evaluation of the ideas.

1.4.1 Literature Review

Literature review is carried out to identify the gap in the research area. The review explores product quality topics in the Product Development Process related to product

non-conformance in pre-production. Special attention is given to the work concerning non-conformances and validation practices. Chapter 2 is dedicated to a review of the literature.

1.4.2 Industrial Investigation

This is a qualitative research based on the study of a consumer electronic product to illustrate and analyse evidence of non-conformances and product validation practice in pre-production. The study involves a multinational company designing and producing home audio products, where the researcher has been working in the pre-production section. Chapter 3 investigates, illustrates and presents non-conformances and product validation practice in depth.

1.4.3 Development of Research Ideas

The formulation and development of the research ideas had evolved from the understanding of the issues in product non-conformance and validation process in pre-production, and the extension of current works on quality and process improvements. Chapter 4 describes the development of the research ideas.

1.4.4 Deployment of Research Ideas

The deployment of the research ideas into the product validation process is through a structured validation workbook. Details of the deployment of the ideas are described in Chapter 5. A full printed version of the workbook is given in Appendix B.

1.4.5 Evaluation of Research Ideas

Evaluations through interviews are conducted with experts from manufacturing companies who have authority in the product development process and involved in product validation. The evaluations are carried out in two phases: Phase 1 – Evaluation of conceptual ideas; and Phase 2 – Evaluation of deployment and applicability of the ideas in the product validation process through validation workbook. Schedule of

questions for the interviews are formulated using closed and open-ended formats. The evaluations and results of the interviews are discussed in Chapter 6.

1.5 OUTLINE OF THESIS

The thesis is outlined as follows: Chapter 1 provides an introduction to the research. Chapter 2 reviews relevant literature within the research theme and explains the key issues of non-conformances. Chapter 3 illustrates and analyses industrial evidence of non-conformances. Chapter 4 presents the research ideas, followed by the deployment of the ideas in Chapter 5. Chapter 6 reports the results of industry evaluation, and finally, Chapter 7 concludes the research. The structure of the thesis is shown in Figure 1-2.

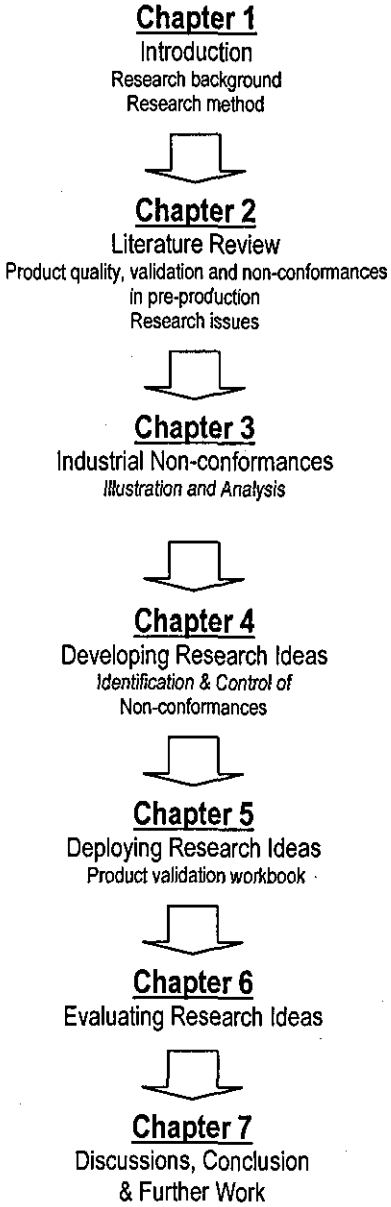


Figure 1-2 Thesis structure

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

This chapter presents the main topics currently researched and related to the main theme of this thesis, non-conformances in pre-production. It also provides background information for further discussion in the following chapters.

The chapter consist of four main sections. Section 2.2 presents an overview of topics on product quality in the Product Development Process relevant to the research theme. Section 2.3 describes current work on product validation in pre-production. Section 2.4 reviews current understanding on product non-conformance in pre-production. Section 2.5 describes the key research issues of product non-conformance in pre-production.

The review realised in this chapter identifies the gap between the proposed research and previous work, followed by an industrial case study which provides the justification for this research highlighted in the next chapter.

2.2 PRODUCT QUALITY IN PRODUCT DEVELOPMENT PROCESS

A successful manufacturing company produces the right products, with the right quality, at the right cost, and in the right time in the very shortest period possible (Zairi, 1995). The driver for producing products with the right quality is conformance to requirements (Crosby, 1979), in particular the customer's requirements. For that reason, companies displayed the *'Certificate of Conformance'*, declaring their products achieved the quality and met customer requirements (Arter, 2003; Parnas and Lawford, 2003). In contrast, non-conforming products are considered as failures to deliver what the customer requires. The consequences of non-conformances are very costly and even

affect company's reputation. In order to avoid and reduce the consequences, understanding the aspects related to product quality and addressing product non-conformance is necessary in Product Development Process.

2.2.1 Product Quality

The International Standardisation Organisation (ISO9000, 2000) defines product quality as '*the totality of features and characteristics of a product that satisfies the stated or implied needs*'. However, there are other definitions of product quality. Popular definitions of product quality are "conformance to requirement" (Crosby, 1979), "what the customer needs at a price the customer is willing to pay" (Deming, 1986), and "fitness for use" (Juran and Godfrey, 1999). Further breakdown of these definitions describes product quality as having the following characteristics (Duffin, 1995; Waller and Ahire, 1996):

- *Fitness for use* – the product serves the utility needed by the application or the user, when used for its intended purpose.
- *Performance* – the product performs its intended function, operating properly, effectively and efficiently.
- *Features* – the product has additional capabilities, other than the main function, which make use easier or more satisfying.
- *Conformance* – the product meets specifications in terms of fit, form and function.
- *Reliability* – the ability of the product to perform over time without breakdown or failure, through the absence or ineffectiveness of failure mechanisms during the expected operating life or under stated conditions of use.
- *Durability* – the ability of the product to last a long time before it physically deteriorates or until replacement is preferable under expected conditions of operation and maintenance.
- *Serviceability* – the ability of the product to be easily and quickly maintained and/or repaired.
- *Aesthetic appeal* – how the product pleases in terms of appearance, and/or how it satisfies in terms of feeling in use, such as styling, comfort, balance, etc.

- *Robustness* – insensitivity to common cause variability in the manufacturing process and to the expected range of operating conditions in operation, which can be extended to include extreme conditions of use or abuse.

These quality characteristics are also known as 'Critical to Quality' (CTQ), and when the quality is not met, it can be perceived that one or a few CTQ do not meet customer requirements (de Mast, 2004). However, some of these CTQ may be less significant, measurable or relevant in some contexts than in others (Waller and Ahire, 1996). For example, in Original Equipment Manufacturer (OEM) products such as spark plugs and internal hard disk drives, the aesthetics may not be critical. Also, additional features may not be available in entry level or low end products. Serviceability may not be feasible because it is cheaper to replace rather than service.

It can be seen that the common aspect obvious in these quality characteristics is that it is customer-needs oriented or as-perceived-by customers. It is common for companies to have slogans such as "customer first", and established customer centres to cater to the "voice of the customer" (Hassan et al., 2000). Failure to build and deliver the quality characteristics into products, according to customer requirements, jeopardises the success of the development and subsequently the company's competitive advantage (Ho, 1995). This is reflected in product development time being seen as disrupting speedy time to market, and consequently increasing development cost (Phillips et al., 1999; Brennan, 2001).

The challenge to companies, though, is to identify holistically the factors which cause the failures and to ensure quality characteristics are build into products before they reach the customers. This is imperative, so that appropriate action and control are taken so as to deliver the products which fulfil customer requirements.

2.2.2 Quality Deficiencies

In theory, as the product evolved, uncertainties and known quality deficiencies should have been known and resolved, hence probability for abnormality is very rare. However, in reality this is not the case. In product design and manufacture, about 80% of product quality achieved during development and 20% during production (Winchell,

1996), yet known and repetitive quality deficiencies are still identified in later stages of development, during production, and when products are in use by customers (Swift et al., 1999; Booker, 2003). Surveys have shown that about 70% of product quality deficiencies are development-related, and increases to 90% if that includes problems that could have been avoided earlier in that stage through stricter quality control (Wada, 1996). As a consequence, companies spend a lot on warranty claims, after-sales services and activities, and in some cases suffer from very high product liability charges (de Theiji et al., 1998).

Product quality deficiencies are known to arise from three sources: complexity, variation, and mistakes (Hinckley, 1997). Increasing complexity and variation of products and the production process are due to the rapid advances in electromechanical systems, computer technology, and materials and processing technology (Chao et al., 2004). Excessive complexity and uncontrolled variation result in increasingly difficulty to understand products and the production processes, and hence, subsequent vulnerability to deliver each and every element of CTQ appropriately. Whilst mistakes are seen as the major source of quality deficiencies (Hinckley, 1997; 2001; 2003), the consequence is significant. For example, it is reported that "*6.5% of the patients entering hospitals experience adverse drug effects caused by prescription mistakes, the seriousness of these mistakes is highlighted by the fact that 1% of the adverse drug effects resulted in fatalities*". A study has found that of 23,000 production defects, 82% originated from mistakes (Hinckley and Barkan, 1995; Hinckley, 1997), and most of the mistakes are human-generated (Nikkan Kogyo Shimbun, 1988). Hence, these are the events that contribute to the undesired consequence.

In fixing quality deficiencies, people, time, and resources are spent on non-value added activities. For example, correcting errors, finding out where things are, finding out why things are late, checking and double-checking things we do not trust, rectifying and reworking designs, apologising and explaining to customers, clearing up scrap and returns, and making good on warranty and claims (Ho, 1995). These activities are reflected in cost of product quality.

2.2.3 Cost of Poor Quality

Addressing product quality and non-conformances in monetary terms gives greater impact on the management and employees, as it is concerned with financial performance of a company (Chen et al., 2006). Product quality can be measured monetarily using a method called Cost of Quality or COQ (Schiffauerova and Thomson, 2006). COQ is associated with preventing, finding and rectifying quality deficiencies (Mukhopadhyay, 2004). Studies have shown that COQ is imperative to companies financially. For example, 30% of total US manufacturing costs represent COQ (Chen et al., 2006), IBM reported that its COQ is between 20% and 40% of annual revenue, and Avon claimed that "*the cost of building quality into the product is 5% of sales, while the cost of non-conformance is 20%* " (Harrington, 1999). Crosby (1995) classified COQ in two categories,

1. Price of Conformance (POC), the costs of ensuring that products produced are free of defects and deficiencies.
2. Price of Non-conformance (PONC), which includes the costs incurred as a consequence of quality deficiencies.

POC is regarded as Prevention Cost, hence it adds value to companies through value added activities. In contrast, PONC is cost incurred by activities for detecting and rectifying failures, quality deficiencies or non-conformances, therefore it adds cost to Appraisal Cost and Failure Cost (Giakatis et al., 2001). By investing more in prevention activities, the PNOC can be minimised. Examples of POC/PNOC and their related activities are listed in Table 2-1, and Appendix A lists the elements of COQ in product development and manufacturing.

Table 2-1 Type of quality cost and associated activities.

Type of Quality Cost	*Activities*
POC Prevention Cost	• Preparing quality manuals, procedures, different specific plans, etc. • Reviewing quality specifications of new products • Evaluation of suppliers and survey, etc. • Market research and studies to identify customers' requirements • Developing, conducting and maintaining training programmes • Studying process capabilities and developing process control devices • Formal quality improvement programmes • Auditing of the quality system • Calibration and maintenance of inspection and test equipment used in production departments and laboratories to evaluate quality
PONC: Appraisal Cost	• Inspection and testing of quality of purchased products • Inspection and testing of in-process products • Inspection and testing of finished products • Materials consumed or destroyed during inspection and testing • Evaluation of stock for its degradation and evaluation of product at customer end
Failure Cost	• Scrap • Rework, repair and reprocessing • Re-inspection and retest to verify the quality requirement after rework or reprocessing • Failure analysis • Losses • Downgrading of product • Downtime (idle facilities due to quality failures) • Settling customer complaints due to poor quality • Product rejected or returned • Loss of sales • Marketing errors • Product recalls and product replacement • Warranty claims • Allowances (cost of concessions made customary due to poor quality)

Source: Mukhopadhyay (2004)

Instead of using the term COQ, academics and practitioners adopt the term 'Cost of Poor Quality' or COPQ (Harrington, 1999; Juran and Godfrey, 1999; Chen et al., 2006) because it corresponds explicitly to the real effort - reducing or eliminating the non-value-added costs and waste (Shingo, 1986) associated with quality deficiencies and non-conformances. The COPQ is seen as a useful tool in understanding about quality deficiencies for:

- getting the management and employees' attention in monetary terms, and on the need to understand the cost of poor quality they produce,

- providing better return on the problem-solving efforts, so that the solution is directed at bringing maximum financial return at the lowest possible cost, and
- providing a method of measuring the effect poor quality has on the organisation, and the impact of quality improvement initiatives (Harrington, 1999).

Hence, quality deficiencies and non-conformances contribute significantly towards the performance of companies financially, and subsequently affect the company's competitiveness.

2.3 PRODUCT VALIDATION IN PRE-PRODUCTION

This section consists of two parts describing current work on product validation in pre-production. The first part provides an overview of pre-production, its characteristics, and its significance to the product development process and manufacturing. The second part presents the definition of the product validation process, its purposes, and the considerations in assessing products in pre-production.

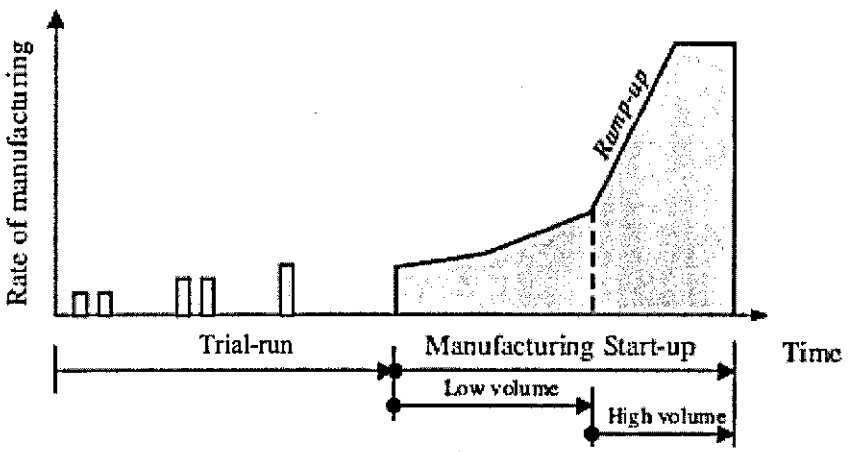
2.3.1 Pre-production

Manufacturing industry is experiencing an accelerated rate of product introductions. This makes the pre-production more significant then ever (Terwiesch and Bohn, 2001). The study on pre-production is imperative because this is the final review phase in the Product Development Process before products are released for full-scale production. Works on pre-production specifically on product non-conformance, which is the main theme of this thesis, have not proliferated. However, several publications related to pre-production significant to the research theme are presented.

In pre-production, a new or derivative product is reviewed for its feasibility to be produced with the available production resources in a manufacturing facility (Popplewell and Bing, 1995; Riedel and Pawar, 1997; Shepherd and Ahmed, 2000). The review is in preparation for smooth running and trouble-free production (de Theije et al., 1998). The preparations among others are,

- determining production activities and flow,
- generating production drawings and procedures,
- preparing administrative and quality control procedures for production,
- producing a 'first commercial product', in the case of full-scale production, a trial-run arranged; the difference between trial-run and full-scale production is depicted in Figure 2-1.

In an assembly plant, the pre-production function is to facilitate new product introduction and production trouble-shooting, as described in Chapter 3. This includes all the tasks necessary from setting the master schedule to commencing the full-scale production. Some of the tasks are design, process and assembly planning; production planning and control; and material and component purchasing (Popplewell and Bing, 1995). For this reason, pre-production is sited close to the production facility so as to replicate the actual production conditions such as assembly operations, product assemblers, material supplies, and assembly lines.



Source: Almgren (2000)

Figure 2-1 Difference between trial-run and production start-up

Product under review is known as 'pre-production prototype' or 'pilot production prototype' (Ulrich and Eppinger, 2003). This product is limited in quantity, short-run as the first output of the production process, and not at full capacity. However, some researchers call the product 'trial-run product' because the product's producibility is still under study (Peters et al., 1999). The trial-run assesses the product either to cater for production capability or adjusting production to cater the product's design specification and quality requirement. Besides, 'disturbances' affecting the product's

final validation are identified and solved in the trial-run before the start of full-scale production. Such disturbances may, if they are not prevented or their effects controlled, result in quality and quantity losses during start-up, and an increased cost of production (Almgren, 2000).

In pre-production, products are reviewed by way of validation. The validation takes into account several considerations (Riedel and Pawar, 1997) such as,

Production control	*Production processes*	*Standardisation*
Labour requirements	*Product quality*	*Engineering design*
Machinery	*Product cost*	*Development costs*
Plant	*Functional requirements*	*Styling/appearance*
Assembly techniques	*Materials*	*Existing products*

There are several activities associated with validation in pre-production. These activities consider the feedback from customers for '*optimal progression*' towards the full-scale production. The feedback is important, so that unforeseen requirements and circumstances can be addressed before the production begins (Ulrich and Eppinger, 2003). These activities are

- *trial production*, to confirm the manufacturing and assembly processes necessary to produce the product, and that the production equipment is capable of maintaining the specifications required for the product.
- *batch testing,* to confirm that the product complies with the specifications laid down.
- *alpha testing,* to confirm the physical requirements of the product, as well as its production/assembly suitability.
- *beta/gamma testing,* to gauge the reactions of existing customers or cold testing of the product on potential customers.

However, not all the activities are applicable in manufacturing industry. For example, for 'white products' such as the home appliances and consumer electronic products, an out-of-box inspection (Thelin, 1993; Arter, 2003), and trial-run are carried out, as described in the Chapter 3, but the alpha, beta and gamma testing are not conducted. However, these tests are common for computer hardware and software products. Once the activities and validation are completed, and the requirements for the start of production have been approved, manufacturing start-up begins.

In summary, studies on pre-production have not been prolific. Although mentioned in articles on the Product Design and Development process, it described only in general as compared to its significant role as the last checkpoint before products are released for full-scale production. The reasons for pre-production are validation and verification of products prior to production, while the ultimate aim is to ensure product quality and reliability (Jamaludin and Young, 2005). Pre-production is constrained by

- *new product introduction push*, which is the accelerated rate of product introductions into the market,
- *production pull,* which demands product for full-scale production on a tight schedule, and
- *disturbances* such as operational issues and existence of product non-conformance.

Despite these constraints, the outcome of pre-production may result in products not being able to proceed further downstream (production), disrupts upstream activities (design and development), and these consequences increase cost to the company.

The research focuses on the disturbances which is product non-conformance. The research formulates and introduces a rapid approach in identifying and controlling product non-conformance. The next section describes the validation aspect, followed by an overview of non-conformance in pre-production.

2.3.2 Product Validation

Many publications discuss validation in the context of quality, product development process and manufacturing performance (Krishnan and Ulrich, 2001; Alexander and Clarkson, 2002; Karapetrovic and Willborn, 2002). Validation, being a method of performance assessment, is typically explained under the heading of review, evaluation or audit (Phillips et al., 1999; Gonzalez and Barr, 2000; Arter, 2003). This thesis considers new products are reviewed by means of validation in the pre-production stage of the product development process to ensure they meet the specification and quality requirements.

In the literature, there are several ways of describing validation. ISO 9000 defined the outcome of validation as *"confirmation through evidence that the requirements and fitness for use for a specific intended application have been fulfilled"* (Karapetrovic and Wilborn, 2002). Ebert et al. (2001) described validation activities as identifying non-conformance and the need to differentiate between the cause of non-conformances and what would be related to non-conformance characteristics. Validation can also be seen as determining whether the strategies implied into the design, to conform to specification and quality requirements, are optimised (Phillips et al., 1999). In other words, validation can simply mean answering the question, *"Have we built the right thing?"* (Boehm, 1981, cited in Kim et al., 1999; Alexander and Clarkson, 2002). To ensure the right product is built, products are validated in pre-production prior to full-scale production and release to customer.

Other than to determine the right product is built, the purpose of validation is to ensure smooth transition of the detailed design through to the finished product and its production process (Peters et al., 1999). The validation process attempts to:

- determine the product conforms with the design specification, such as the functional and aesthetic, and the necessary statutory compliance requirements.
- assess the capability of the trial-run production process when producing these products to bring together all the components of the production system, including materials, processes, tooling, vendors, and personnel (Terwiesch et al., 1999; Aw, 2005),
- identify abnormalities or unpleasant surprises that might occur in the product and during the mass production stage (Aw, 2005).

In the effort to meet the above purposes, several considerations are looked into during validation. There are two categories of validation considerations. The first are the *generic considerations* (Fairlie-Clarke and Muller, 2003) which divide into two types: technical and commercial. The second considerations are based on the *priority ranking* (Riedel and Pawar, 1997). A summary of these categories is given in Table 2-2. It can be seen that the second considerations are product-oriented, whilst the first are categorised as operational-oriented.

Table 2-2 Validation considerations

Generic considerations		*Priority ranking considerations*
Validating technical aspects	*Validating commercial aspects*	Product quality Assembly techniques Production processes Plant Machinery Engineering design Development costs Styling/appearance Functional requirements Labour requirements Production control Materials Standardisation Existing products
Model Prototype Product against specification Production trials Obtain certification User/field trials	Product concept Marketing Price Manufacture cost Forecast sales	

Source: Fairlie-Clarke and Muller (2003); Riedel and Pawar (1997)

Besides those considerations listed above, Ulrich and Eppinger (2003) suggests that validation takes into account the feedback from customers as well. In this way, feedback is given so that unforeseen requirements can be addressed before the company starts full-scale production. Therefore, another type of validation consideration is based on the pre-production activities, such as the trial production, and alpha, beta and gamma testing as described in the previous section.

Not all kinds of products undergo all the above activities, as they are expensive undertakings and time-consuming. In the context of consumer electronic products such as televisions and stereo-systems, trial-run is the most common validation activity in pre-production. From the three types of consideration described above, product validation consideration differs and is associated with three business activities - the design, the production and the commercial, and can be depicted as shown in Figure 2-2. A brief description of the differences in each consideration is as follows,

- *design consideration,* relates to product specifications, requirements, quality and reliability,
- *production consideration,* relates to the production process,
- *commercial consideration,* relates to customer acceptance of the product deliverables, such as concepts, price, support, and styling.

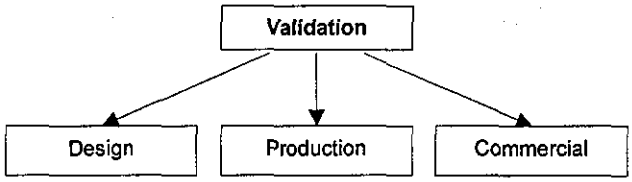


Figure 2-2 Three main considerations in product validation

As mentioned earlier, in pre-production, products are validated by means of inspection and testing. The ISO 9003 emphasis on final inspection and testing requires that all the inspection and testing have been completed prior to production and release to customer (Bradley, 1994; Ho, 1995; Yahya and Goh, 2001). Although inspection activity is seen to be wasteful since it adds cost but not value (Ishikawa, 1985), it is recognised that, as long as product and processes are producing non-conformances, inspection will be necessary (McCarthy et al., 1996). In addition, non-conformances create the need for inspection and an effective tool for discovering, reducing and eliminating non-conformances, provided that its feedback is properly used (Ghinato, 1998). In pre-production, the inspection is characterised by the following conditions:

1. short duration of time allocated for the inspection of small number of products and trial-runs (Aw, 2005),
2. inspection focuses on the 'out-of-box' features and assembly process of the final product (Thelin, 1993; Arter, 2003).

These conditions are described in Chapter 3, in an industrial case study. Hence, the goal of inspection in pre-production is to assess the quality of a product in question, not the quality of the process used to develop the product (Parnas and Lawford, 2003). The outcome of the inspection would determine if the product was qualified for full-scale production or failed to qualify, hence redesign or modification is needed and the validation is reiterated (Aw, 2005). When the product is non-conforming, corrective action has to be taken, and the inspection is reiterated to validate that the non-conformances are resolved. This thesis is inclined to inspection as an instrument for the product validation process.

In summary, the importance of validation of products in pre-production is well accepted, however many problems still exist in the move from the pre-production stage through to

that of full-scale production. There has been a lack of methodological principle of how the validation process in pre-production can rigorously identify and control product non-conformance (Almgren, 2000; Nagasaka, 2000; Liu and Cheraghi, 2006). This is an area being researched in this thesis.

The next section explains the understanding of product non-conformance in pre-production.

2.4. CHARACTERISTICS OF PRODUCT NON-CONFORMANCE

This section reviews current understanding on product non-conformance in pre-production, and it has four sub-sections. The first introduces the definition of non-conformances. The second discusses the sources of non-conformances, followed by the explanation of mistakes as the major contributor to non-conformances. The fourth reviews the methodologies for controlling non-conformances.

2.4.1 Defining Non-conformance

Garvin (1984) (cited in Waller and Ahire, 1996) and Griffith (1996) (cited in Liu and Cheraghi, 2004) defined non-conformance as *"the departure of a quality characteristic from its intended level or state that occurs with a severity sufficient to cause an associated product or service not to meet a specification requirement"*. Johnson (1989), cited in Backstrom and Doos (1997) defined non-conformance as '*undesired event*', and elaborated further, as having the elements of loss in quality such as defect, imperfection, flaw or failure. In other words, the term non-conformance is simply the antonym of the term conformance. A product is conforming if it meets the form, fit/assembly and functional specification (Juran and Godfrey, 1999; Arter, 2003). In pre-production, if a product passes validation, the product is said to be conforming. In contrast, a product is non-conforming if it does not meet the specification, and when this condition occurs, the product fails validation. This thesis considers non-conformance as any deviation from specification affecting the quality of products.

Non-conformances are characterised either by attribute or variation (Murthy and Blischke, 2006) in which the former involves a 'binary-valued description'; that is, whether an item meets a desired value or not; whilst the latter involves a 'continuous-valued description', where an item is measured over an interval. This thesis focuses on non-conformances characterised by attribute, since in pre-production a product cannot be validated continuously over a long period, and the number of products to be validated is significantly small. Furthermore, non-conformances caused by variation are best described in the context of product reliability when the product fails over time (Dillon, 2005; Murthy and Blischke, 2006), whereas the context of this research is on product quality, specifically related to product failure due to non-conformance.

Researchers and industrialists associate quality problems with non-conformances (Crosby, 1979; Deming, 1986; Juran and Godfrey, 1999). They argued that product quality problems and non-conformances are defined by the customer. Companies go to the extent of displaying the '*Certificate of Conformance*' certifying that their products achieved the quality and meet customer requirements (Arter, 2003). This shows that companies take the issue of non-conformances very seriously whilst trying their level best to deliver what the customer needs.

Juran and Godfrey (1999) described two types of product quality problems and the approach in confronting them:

- *Sporadic problems are defined as an abrupt departure from the status quo, e.g. a company experiences a sudden jump in per cent of substandard from the company's usual 5% to 15%; the identification and correction of these problems are in the domain of quality control.*
- *Chronic problems are those present in the status quo, e.g. if the same company decided that the usual 5 % substandard is unacceptable and must be lowered; the identification and correction of these problems are in the domain of quality improvement.*

It can be seen that, in pre-production, unanticipated non-conformance can be a sporadic problem, while anticipated non-conformance can become a chronic problem.

Many works described non-conformances either from a broad or narrow aspect. The broad aspects of non-conformances were examined in the context of overall Product Development Process, with cost as the main driver. For example, many researchers associating non-conformances with the Product Development Process often relate the implication towards the Cost of Quality, or the Cost of Non-conformance (Crosby, 1979; Feigenbaum, 1991; Juran and Godfrey, 1999), while the narrow aspects of non-conformances were described as very specifically oriented towards mathematical, computational, or statistical methods of analysis and problem-solving. For example, the analysis of misalignment using expert rules (Das and Gami, 2004), and material failures using the finite element and the boundary element methods (de Castro and Fernandes, 2004).

Non-conforming products are also part of a business risk, or specifically, a technical risk (Klein and Cork, 1998; Jaafari, 2001). The consequences of risk from sub-standard quality products for an organisation, among others, are the high cost of recovery, lost of consumer trust, and competitive disadvantage (Belliveau et al., 2002). Hence, to reduce the risk, non-conforming products should be analysed to help companies decide, "*whether to explore particular non-conformance in more or less detail and how much time, money, resources to invest in response to particular conformance*" (Ward, 1999).

In summary, throughout Product Development Process, a product undergoes a series of reviews. As a product reaches the production stage, conformances are met and non-conformances are removed, which can be depicted as shown in Figure 2-3. Non-conformances have to be understood holistically before products are released for full-scale production and to customers. Rigorous validation is vital to ensure that non-conformances are identified and removed. Hence, the main reasons for identifying non-conformances are to ease identification and elimination of the causes and the consequences, and to minimise rectification cost.

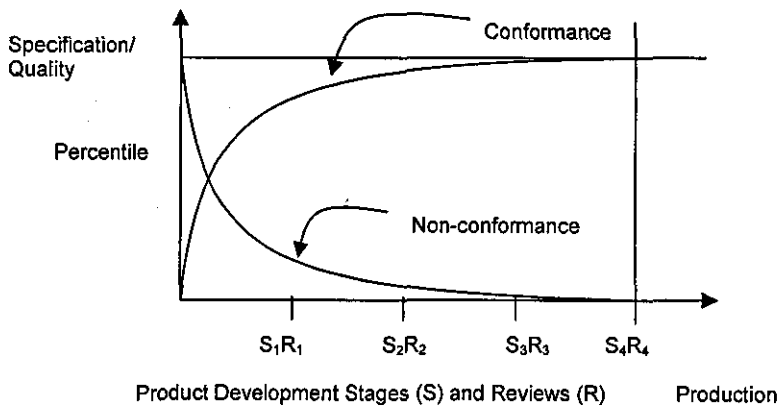


Figure 2-3 Correlation between conformance and non-conformance

2.4.2 Source of Non-conformances

Hinckley (2001) identifies complexity, variation and mistakes as the sources of product non-conformance. The following paragraph provides the differences between each source.

Complexity

In Merriam-Webster's Dictionary (2006), the general term 'complex' is defined as (1) composed of many interconnected parts, compound, or composite, (2) characterised by a very complicated or involved arrangement of parts or units, and (3) so complicated or intricate as to be hard to understand. Suh, (2003) specifically described complexity, in the functional domain as *"a measure of uncertainty in achieving functional requirements, which may be a set of design objectives, research questions, and project goal"*. These definitions imply that as complexity increases, the expected tendency of non-conformance rate should also increase (Hinckley, 2001). For example, as product and part complexity increases, it also reflects in the increase complexity in assembly operation (Beiter et al., 2000). Thus, a product with 1000 parts to have more non-conformances than one with just 10 part, or a complex product with 10 parts (e.g. a calculator) to have more non-conformances than a simple product with 1000 parts (e.g. a bicycle).

Complexity is measured by time - time to design, procure, fabricate and assemble products; likewise in assessing complexity. For example, it takes time to decide and assemble, between a bolt and a snap-fit. The longer the time to complete a task is linked with the difficulty of the task, therefore it is also linked with the frequency of non-conformance (Hinckley, 2001). Thus, the way to reduce complexity or non-conformances is simplicity in design. Hinckley (2001) and Suh (2003) explained in depth and suggested ways to reduce complexity in the manufacturing system.

Variation

A significant proportion of non-conformances can result from variation, and when detected too late, *'the result is a costly affair'* (Morup, 1994, cited in Swift et al., 1999; Booker et al., 2005). For example, variation in product tolerances affects customer satisfaction, production activities, and design processes. Gerth and Hancock (1997) cited in Swift et al. (1999), claim that most of the causes of scrap, rework and warranty returns came from wrong selection of tolerances.

Variation can be controlled by observing (1) the outcome of every repeated action that falls within three standard deviations in Statistical Quality Control (SQC) (Hinckley, 1997), (2) within six standard deviations in Six Sigma (Phillips et al., 1999; Pfeifer et al., 2004; Senapati, 2004), or (3) the Taguchi's experimental method (Antony et al., 2001). Variation can also be eliminated with settings, for example, the infamous Single Minute Exchange of Dies (SMED) technique (Shingo, 1985), automated adjustment, or using Statistical Process Control (SPC) (Hinckley, 2003).

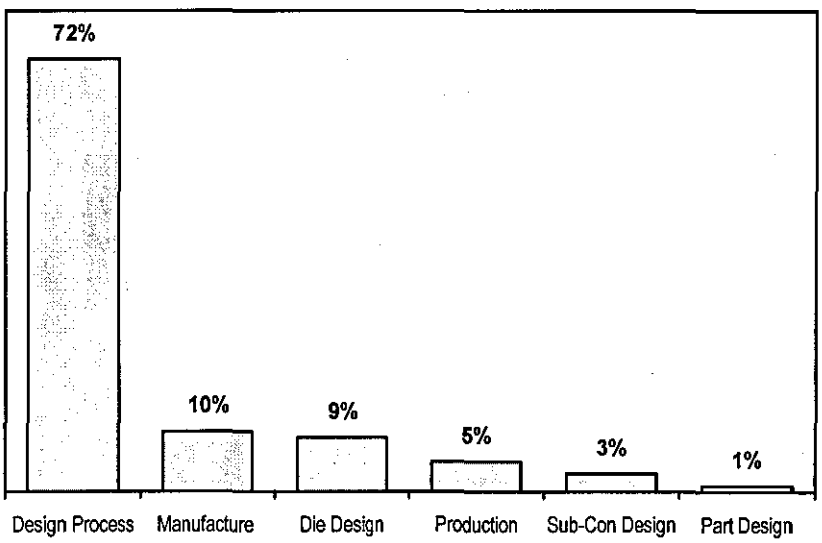
As variation requires a continuous observation of large sample size before any controls can be decided, it is impractical to observe too small samples in pre-production using either SQC or Six Sigma. In pre-production, normally the number of products available during a session of validation is between 5 to 10 units only, as described in case study in Chapter 3.

Assessing complexity and variation during the pre-production stage is difficult, since the session for validation is too short and the sample size is too small. In

addition, at this stage, most design decisions have been finalised after considering the complexity and variation aspects.

Mistakes

While other researchers argue that variation is the major cause of quality problems, Hinckley (2003) has proved mistakes are the major cause, while complexity is the root source of quality problems. However, mistakes made most of the totality of non-conformances rates in manufacturing (Hinckley, 2003); similarly, in development, most non-conformances are caused by mistakes (Nikkan Kogyo Shimbun, 1988; Hinckley, 2001). Rook (1962) cited in Hinckley (2003), discovered that 80% of 23,000 production problems originated from mistakes. Chao et al. (2001) conducted an interview in one company and found that more than 70% of the company's quality losses attributed to mistakes were made during the design or development process, (see Figure 2-4).



Source: Chao et al. (2001)

Figure 2-4 Sources of quality loss due to mistakes

In pre-production, products are to be validated in small quantity, in a short time, and the validation considerations are limited to the major aspects of the product. The case study in Chapter 3 describes validation considerations based on

1. 'out-of-box' compliance as perceived by customers, and
2. trial-run assembly requirement as perceived by the production.

At this stage, complexity and variation may not be significant, therefore any deviation from specification and loss of quality during the validation are mostly due to mistakes. This research will focus on mistakes as the major source of product non-conformance.

2.4.3 Mistakes as Major Source of Non-conformances

Several works which described mistakes classifications in Product Development Process are listed in Table 2-3. However, there are deficiencies in the classifications, such as too simplistic, not easily understood by individuals in manufacturing and design, the classified mistakes can not be detected, elimination of the factor does not eliminate mistakes, and does not lead to direct identification of appropriate control methods (Hinckley, 1997, cited in Chao and Ishii, 2004).

Whilst most of the classifications are based on the causes, Hinckley, (2001) classifies mistakes based on the outcome or *consequence of mistakes* rather than the causes. The Outcome-based Classification, consist of five classes of consequence of mistakes, as listed in Table 2-4. The classification describes the consequence of mistakes which are related to the production.

Since product validation is the main activity in pre-production, as the name implies, validation is strongly oriented to the production. Therefore, any non-conformances identified during validation are production-related. By identifying production-related non-conformances, quality problems can be detected and prevented earlier before production. This research has seen that the Outcome-based Mistake Classification is appropriate for describing mistakes which cause product non-conformance in pre-production.

Table 2-3 Various classifications of mistakes

Classifications	*Example*
Mistake-Proofing Classification	Forgetfulness, mistakes due to misunderstanding, mistakes in identification, mistakes made by amateurs (Nikkan Kogyo Shimbun, 1988)
Classification of Human Performance in Industry	Planning, designing and developing, producing, distributing (Harris and Chaney, 1969)
Performance Shaping Factors	Inadequate lighting in work area, inadequate training or skill, poor verbal communication (Meister, 1999)
Human Reliability Assessments/Human Mistakes Probabilities Classification	Mistakes of omission, commission (selection, sequence, time, and qualitative mistakes) (Swain, 1990)
Ergonomic Method	Mistakes during perception stage, decision-making process, and action process (Chao and Ishii, 2004)
Psychological Classification	Slips in formation of intention, from faulty activation of schemas, faulty triggering of active schemas (Chao and Ishii, 2004)
Stress-based Classification	Work load, occupational change, problems of occupational frustration, occupational stress like noise, lighting (Chao and Ishii, 2004)
Task-based Classification	Design, operator, fabrication, and maintenance mistakes (Chao and Ishii, 2004)
Behaviour-based Classification	Perceptual, mediational, communication, and motor processes (Chao and Ishii, 2004)
Design Process Classification	Key design tasks (knowledge, analysis, communication, execution, change, organizational) (Chao and Ishii, 2004)

Table 2-4 Outcome-based Mistakes Classification

Class	*Description*
Defective Material	Material *entering* a process is defective; inadequate for intended function, process, or purpose.
Information Mistakes	Ambiguous information; incorrect information; misread, mis-measure, or misinterpret; omitted information; inadequate warning
Misses	Correct operation performed, but accuracy of motion control or timing not adequate to result in desired outcome, for example misaligned parts, mis-adjustments, mistimed or rushed.
Omission or Commission Mistakes	*Failure to perform required action or execution of prohibited* action, for example added material or part, prohibited actions, omitted operations, omitted parts, and counting errors
Selection Mistakes	Incorrect selection from available alternatives, for example wrong part, wrong orientation, wrong operation, wrong location, wrong destination

Source: Hinckley, (2001)

Chapter 3 reports an industrial evidence of non-conformances which originated from mistakes. The Outcome-based Mistakes Classification described above is further elaborated in Chapter 4.

2.4.4 Methods for Analysing and Prioritising Non-conformances

This research considers non-conformance as any deviation from specification, affecting the quality of products such as having defect, imperfection, flaw or failure (see Section 2.4.1). In pre-production, when these characteristics are identified, an analysis and control measures are initiated. The analysis is normally based on the severity or criticality of the non-conformance and prioritised appropriately. From the literature survey and industrial practices, current trends show that there are qualitative methods used for analysis and prioritising non-conformances in Product Development Process:

- Failure Mode and Effect Analysis (FMEA)
- Simple Severity Ranking (SSR)
- Reliability and Quality Matrix (RQM)

2.4.4.1 Failure Mode and Effect Analysis

Failure is one of the characteristics of non-conformance. The most widely used failure prioritising and analysis tool in Product Development Process is the FMEA (Chao and Ishii, 2003; Stamatis, 2003). This method considers three aspects to prioritise failures: Severity, Occurrence and Detection. Each aspect has a scale of 1 to 10, representing the 'significance' levels. The complete scales of the three aspects are shown in Tables 2-5, 2-6 and 2-7. The equation of these three aspects produces a priority value called the Risk Priority Number (RPN). Appropriate actions to resolve failures are based on this number (Franceschini and Galetto, 2001; Stamatis, 2003).

Table 2-5 Scaling of Severity.

Severity	*Level*	*Criteria*
None	1	No effect.
Very slight	2	Customer not annoyed. Very slight effect on product or system performance.
Slight	3	Customer slightly annoyed. Slight effect on product or system performance.
Minor	4	Customer experiences minor nuisance. Minor effect on product or system performance.
Moderate	5	Customer experiences some dissatisfaction. Moderate effect on product or system performance.
Significant	6	Customer experiences discomfort. Product performance degraded, but operable and safe. Partial failure, but operable.
Major	7	Customer dissatisfied. Product performance severely affected but functional and safe. System impaired.
Extreme	8	Customer very dissatisfied. Product inoperable but safe. System inoperable.
Serious	9	Potential hazardous effect. Able to stop product without mishap – time-dependent failure. Compliance with government regulation in jeopardy.
Hazardous	10	Hazardous effects. Safety-related, sudden failure. Non-compliance with government regulation.

Table 2-6 Scaling of Occurrence

Occurrence	*Level*	*Criteria*
Almost never	1	Failure unlikely. History shows no failure.
Remote	2	Rare failures likely.
Very slight	3	Very few failures likely.
Slight	4	Few failures likely.
Low	5	Occasional failures likely.
Medium	6	Medium number of failures likely.
Moderately high	7	Moderately high number of failures likely.
High	8	High number of failures likely
Very high	9	Very high number of failures likely.
Almost certain	10	Failure almost certain. History of failures exists from previous or similar designs.

Table 2-7 Scaling of Detectability.

Detectability	*Level*	*Criteria*
Almost certain	1	Proven detection methods available in concept stage.
Very high	2	Proven computer analysis available in early design stage.
High	3	Simulation and/or modelling in early stage.
Moderately high	4	Tests on early prototype system elements.
Medium	5	Tests on pre-production system components.
Low	6	Tests on similar system components.
Slight	7	Tests on product with prototypes with system components installed.
Very slight	8	Proving durability tests on products with system components installed.
Remote	9	Only unproven or unreliable technique(s) available.
Almost impossible	10	No known techniques available.

For specific applications within product design and manufacture, the FMEA is used as a failure analysis tool with a specific name, according to the application. These are the Design FMEA, System FMEA, Process FMEA, Machine FMEA and Service FMEA (Stamatis, 2003), and the most recent is the Total FMEA (Devadasan et al., 2003). Ironically, there are many works criticising this tool (Braglia 2000, Signor 2000, Devadesan et al., 2003), and these are discussed in the context of pre-production in Chapter 4.

2.4.4.2 Simple Severity Ranking

In Product Development Process, defects are commonly determined based on three levels of severity, namely Critical, Major and Minor (Winchell, 1996; Ghinato, 1998). The Military Standard 105-D1963 (US Dept. of Defense, 1999) prioritises non-conformances as critical, major and minor. In pre-production, the three levels define the severity of non-conformances (Winchell, 1996), as follows,

- *Critical non-conformance which is not safe and likely to cause physical injury to people or serious damage to product; not meeting regulations, and failing during service, causing severe customer dissatisfaction.*

- *Major non-conformance which is substandard performance, likely to reduce the ability to perform or did not deliver its intended function, causing customer dissatisfaction.*
- *Minor non-conformance which does not reduce the ability to perform its intended function, and flawed aesthetics, causing dissatisfaction to some customers.*

In the industry, companies prioritise non-conformances based on the same approach, as described in Chapter 3. However, companies adopted different methods of describing the three levels of severity, for example by colour and alphabetical or numerical representation.

This simple severity ranking is unique in a way that the definition, interpretation, and application of the ranking can be customised depending on the company's requirements. In addition, the advantage of this method is that in some conditions, non-conformances can be compromised depending on the seriousness (Ghinato, 1998). The decision to determine the severity of non-conformances depends on the perception, judgement, experience, and discretion of the senior member in the company. However, the major drawback with this qualitative approach is inconsistency in deciding on and control of non-conformances, especially when different people and circumstances exist.

2.4.4.3 Reliability and Quality Matrix

Another simple method for analysing and prioritising non-conformances is introduced. The method is called the Reliability and Quality Matrix or RQM (Yuan, 2002). The RQM is described as follows,

- The RQM is used to indicate the potential reliability/quality problems at various milestones or stage-gates throughout the product development process. The problems are attended to gradually from one milestone to another, until no more possible problems occur. Therefore, the RQM is a tool used to manage the progression of solving reliability/quality problems at each milestone.

- The RQM is described in a two-dimensional matrix, as depicted in Figure 2-5(a). The matrix divides

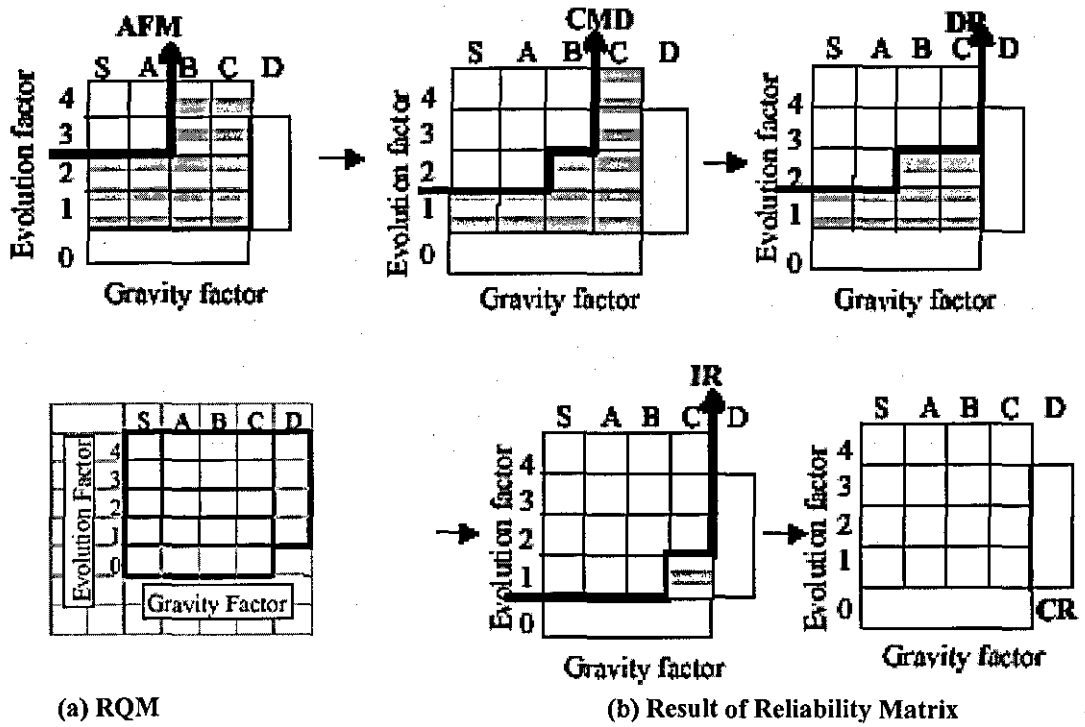
  (1) reliability/quality problems into five 'gravity factors' (represented by columns), according to the severity of the problems, as follows:

  S-problem: non-conformity with safety standard/other safety requirement
  A-problem: a problem that results in a non-producible or non-saleable product
  B-problem: a problem that results in a product that can be produced but with big problems, or will not be accepted by a critical customer
  C-problem: results in a product that can be sold or produced with minor difficulties
  D-problem: problem accepted by management, no activities will be started to reduce or eliminate this problem

  (2) status of the reliability/quality problems into five '*evolution factors*' (represented by rows), as follows,

  4: cause not known
  3: solution not known
  2: evaluation not yet positive
  1: solution not yet introduced
  0: solutions introduced

Figure 2-5(b) depicts that all potential reliability/quality problems are indicated in the matrix according to the 'gravity factors' (severity) and the 'evolution factors' (status of the problems) at milestone AFM. All the problems of type S and A, and with status 4 and 3 are severe problems that need to be solved first by the first milestone (AFM). Other less severe problems (shown by the shaded lines) are solved gradually (shown by the arrows) at subsequent milestones which are CMD, DR, IR and CR. This way, potential reliability/quality problems are managed step-by-step throughout the product development process.



Source: Yuan (2002)

Figure 2-5 Reliability and Quality Matrix and its application

The advantages of this method are:

- identifies and prioritises the problems from the production and customer's perspectives (the gravity factor),
- lists the solution condition to the problem (the evolution factor),
- it is simple and uncomplicated to understand and use.

The RQM is seen as an appropriate method to be used in pre-production because it fulfils the requirement and criteria to analyse and prioritise non-conformances. Firstly as mentioned earlier, the product is validated based on the production and customer consideration, which the RQM described as the gravity factor. Secondly, most non-conformances already have solutions; therefore it will be easier and faster to resolve the non-conformances by re-call and re-use of the solutions, as described by the evolution factor in the RQM. Finally, due to time limitation of each validation session, there is a need for a rapid and easy to use analysis, priority and problem-solving technique; hence, the RQM is seen as a simple and uncomplicated method.

In summary, the use of either FMEA, SSR, or the RQM techniques, determining the status of any identified non-conformances, is in the hands of senior engineers, designers, and departmental/section managers of the company. From the analysis and priority, the appropriate course of action is taken. In general, non-conformances are grouped as (1) the non-conformances needing repair or rework, (2) non-conformances which can be accepted, or agreed by compromise, and (3) non-conformances which cannot be accepted or tolerated. In addition, cost has always to be the determining factor on the course of action in resolving the non-conformances, where the cheapest is the priority.

This research has adapted and customised the RQM method in analysing and prioritising non-conformances explained in the chapter 4.

2.4.5 Methods for Reducing and Preventing Non-conformances

The identification, reduction and prevention of non-conformances from escaping into production are limited by the constraints in pre-production. These constraints are tight schedules from development to production, whereby the time allocated for validation is too short, and the number for products of validation is insufficiently small. In this situation, the validation emphasises identifying tangible non-conformances by way of

1. out-of-box inspection as perceived by the customer,
2. trial-run inspection as perceived by the production line

Tangible non-conformances identified in the two inspections are scrutinised prior to full production. The constraints, the conduct of inspection, and how non-conformances are scrutinised are explained in the case study in a multinational manufacturing company in Chapter 3.

Non-conformances are scrutinised with a strategy to reduce and prevent them from escaping into production. There has been a lack of research in pre-production into how this strategy can be achieved. However, there are well established quality control methods and tools used to control non-conformances. The commonly used methods are quality control tools such as the Design of Experiment (DOE) and the Failure Modes

and Effects Analysis (FMEA) (Peters et al., 1999), and the zero defect approach called Mistake-proofing (Shingo, 1986; Hinckley, 2001). The DOE method emphasises optimising performance, quality, and cost, "*seeking to design a product and process which are insensitive or robust to causes of quality problems*" (Unal and Dean, 1991). The FMEA is the most widely used; however, this tool is complicated, as described in previous section. These methods and tools are seen as continuous non-conformances reduction and prevention instruments for the whole product development programme and practices in a company.

For reducing and preventing non-conformances on the product under validation, Mistake-proofing (*Poka-Yoke* - in Japanese) is seen as appropriate. As the name implies, the method suggests techniques of detecting and removing mistakes. This method adopts full inspection on products, and uses mistake-proofing devices to detect and remove mistakes which cause non-conformance. The method applies two main principles:

1. 100% inspection - products are inspected based on a complete checklist of out-of-box and trial-run inspection item.
2. Inspection method focuses on identifying all known and possible mistakes to ensure they are not missed out, known as Source Inspection.

Mistake-proofing devices are any mechanism which makes mistakes obvious at a glance and prevents them from occurring. Among the devices are guide pins of different sizes, limit switches, jig/fixtures, counters and checklists. Table 2-8 lists the non-conformances manifested from mistakes and the approach to mistake-proofing.

Table 2-8 Non-conformances and mistake-proofing approaches (adapted from Hinckley, 2001).

Non-conformances	MISTAKE-PROOFING APPROACH
AMBIGUOUS INFORMATION Information can be interpreted in many ways, some interpretations may be incorrect.	1. Where possible, simplify task, instruction, or specification. • Minimise number and similarity of parts and tools. • Identify and remove unnecessary material using red tags/marks. • Minimise number and complexity of operations. • Make instruction brief and graphic. • Minimise or eliminate need to add up dimensions and tolerances to fabricate parts. 2. Make labels, messages, instructions, and controls easy to see, read, and reach. 3. Limit amount of information available. 4. Make various types of information distinctly different. • Visual-group related items and distinguish by colour. 5. Use pictures, videos, graphics, or drawings to identify complex parts and clarify complex operations.
INCORRECT INFORMATION Information provided is incorrect.	1. Prevent spurious information. 2. Ensure that instructions cannot be skipped or repeated. 3. Use checklist to verify that results match predictions or requirements. 4. Review instructions and information for accuracy. 5. Have several individuals with diverse backgrounds review instructions and specifications to identify and eliminate potential ambiguity. 6. Look-alike parts must have drawing numbers that differ.
MISREAD, MISMEASURE, OR MISINTERPRET Gauge-reading errors, errors in measuring, or errors in understanding correct information.	1. Make interpretation easy: • Drawings, pictures, or videos illustrate complex parts, concepts, or operations. 2. Print required dimension guide on worksheet.
OMITTED PARTS AND COUNTING ERRORS Missing part or wrong number of parts resulting from counting error.	1. Eliminate parts by combining functions with other parts. 2. Make part omission errors and counting errors obvious. 3. Layout makes missing parts obvious (remainder method). 4. Prevent operation if part is missing.
OMITTED OPERATIONS Failure to perform required operation.	1. Prepare standard procedure charts. 2. Create and use operation checklist. 3. Eliminate need for operation, for example, by simplifying product or process. 4. Make omitted operations visible and obvious, for example, detect omission of operation by comparison to correctly completed items
WRONG PART Part selected, but wrong part.	1. Change design so that same part can be used in right- and left-hand locations. 2. Look-alike parts at each work station minimised, eliminated, or non-interchangeable. 3. Interference prevents assembly of similar but wrong part. 4. Identical parts made of dissimilar material clearly marked.
WRONG ORIENTATION Part inserted in correct location, but part has wrong orientation.	1. Where possible, make parts symmetrical, e.g. end-to-end symmetry. 2. Make parts asymmetric, and make the asymmetry obvious (shape/dimension), 3. Interference prevents setup or assembly of asymmetrical parts in wrong orientation.
WRONG OPERATION Operation executed, but wrong operation used.	1. Mistake-proof selection of instruction and have only one instruction visible at a time. 2. Single design used for both right- and left-hand parts. 3. Redesign, making control setting easy to read. 4. Standard procedure chart guides selection of correct operation.

(continued)

Table 2-8 (continued)

Non-conformances	MISTAKE-PROOFING APPROACH
WRONG LOCATION Part insertion or process execution in *incorrect location that is not result of* incorrectly orienting parts.	1. Simplify design to eliminate inserting (retrieving) parts or materials in wrong location. 2. Change design so that one part fits all locations. 3. Reduce types of fasteners. 4. Interference prevents insertion in wrong location (shape or dimensions). 5. Asymmetrical pin and hole pattern allows only one location. 6. Variety of parts each has a unique shape and mating insertion *feature.* 7. Interference detects defect. 8. *Different cable lengths on wiring harness allow only correct* connections.
WRONG DESTINATION After completing operation, product is sent to *wrong address or destination*	1. Keep destination information linked with product.
WRONG CONCEPT Design-decision errors resulting in incompatible *materials, hazardous products,* non-functional products, or any of wide range of problems. Such errors can also result in products subject to excessive wear, not robust, unreliable, or unsatisfactory to customers.	1. Develop and maintain design checklists unique to specific *products.* 2. Button and switch locations easy to see, and labels easy to read. 3. Parts have adequate constraints. 4. Parts accessible for disassembly and *maintenance.*
DEFECTIVE MATERIALS Material entering process is defective, or inadequate for intended function, process, or *purpose.*	1. Use checklist to verify critical material properties at source. 2. Make defective material unusable or obvious as soon as discovered. 3. For materials that may degrade or fail during processing: • Provide continuous performance monitoring. • Check condition at regular intervals.

Reducing and preventing non-conformances from escaping into production is critical in pre-production. Although constraints and mistakes are unavoidable, non-conformances can be controlled by adopting appropriate methodology, either during the development process or whilst the product is under validation. Thus, the research focuses on identifying and controlling non-conformances.

2.5 ISSUES OF PRODUCT NON-CONFORMANCE IN PRE-PRODUCTION

2.5.1 General Issues

As described in Section 2.4.2, research in pre-production has identified three issues on product non-conformance which are complexity, variation, and mistakes. Research into these issues has addressed ways of

1. reducing complexity (Smoulder et al., 2001; Strauch, 2004; Dillon, 2005),
2. controlling variation (Das et al., 2000; Schippers, 2000; Danese and Romano, 2004), and
3. preventing mistakes (Chao et al., 2001; Dillon, 2005).

Among the three general issues, mistakes made in product development being carried through to production are the main one being explored in this research. Mistakes are seen as the major source of product non-conformance (Shingo, 1986; Hinckley, 2001). Hence, it is crucial to identify and control non-conformances as a result of mistakes and to minimise the consequences in the product development process.

2.5.2 Inadequate Identification of Product Non-conformance

In theory, there should be adequate information, knowledge and understanding of product non-conformance in product development. This includes identifying and controlling non-conformances. Yet there has been a lack of studies and understanding of product non-conformance in pre-production (Almgren, 2000; Liu and Cheraghi, 2004). In addition, there has been no work in the literature on, holistically identifying and controlling product non-conformance caused by mistakes.

A study suggests that 'know-how' on the use and re-use of information and knowledge is critical to verify the design condition (Nagasaka, 2000; Pan, 2001), but it did not explore the know-how to identify and control non-conformances. Another work has developed the 'know-how' to diagnose and recover non-conformances based on a computer system within a manufacturing facility (Liu and Cheraghi, 2004). However, this work described non-conformances without any reference to identifying their causes and consequences. It is argued that before the 'know-how' is formulated, a fundamental issue must be addressed, which is the 'know-what', since knowing the 'what' is the basis to the 'know-how' (Ishikawa, 1985; Deming, 1986; Shingo, 1986). For example, when the causes and the consequences that contribute to non-conformances have been identified, then knowing how to solve and control them appropriately can be formulated. Therefore, once the non-conformances are fully understood, it is easier to formulate a 'know-how' methodology.

One study has attempted to identify the 'know-what' which is the 'quality performance deviation' that affected the final verification process during pilot production and manufacturing start-up (Almgren, 2000). The study identifies two types of non-conformances based on the sources:

1. Materials supply, for example lack of materials, quality of materials, and status of materials.
2. Product concept, for example engineering changes.

However, these sources-based non-conformances are not exhaustive enough in understanding and identifying product non-conformance. These types are either too broad or not critical in pre-production. For example, item (1) may not be a serious deviation as most products are derivative, therefore the materials are similar; and item (2) is best described as 'the response to the deviation' since engineering changes are inevitable as a product is developed and non-conformances are found. Hence, identifying the 'know-what', which is the deviation, the root sources, and the consequences that contribute to product non-conformance, is crucial.

The failure to identify holistically the non-conformances in pre-production is the focus of this thesis. As described in Section 2.4, the best way to identify non-conformances is by

1. identifying the variables of both tangible and intangible mistakes which contribute to non-conformances,
2. correlating these mistakes to the products under validation in pre-production.

Identifying non-conformances enables organisations to benefit from a full investigation of any mistakes (Gillingham et al., 1997). Once non-conformances have been correctly identified, it is much easier to prepare for the control of the consequences and to learn from mistakes.

2.5.3 Deficiency in Methods of Controlling Non-conformances

Failure is one of the characteristics of non-conformances. FMEA is one of the most widely used failure analysis and prioritising tools in PDP (Chao and Ishii, 2003;

Stamatis, 2003) and in pre-production (Peters et al., 1999). Another approach commonly used to analyse and prioritise non-conformances in pre-production is the SSR, where non-conformances are determined by three levels of severity – Critical, Major and Minor (Winchell, 1996; Ghinato, 1998). However, there are deficiencies in both methods and their application, especially in the context of product validation in pre-production.

2.5.3.1 Deficiency in FMEA

There are five types or working levels of FMEA - Design FMEA, System FMEA, Process FMEA, Machine FMEA and Service FMEA (Stamatis, 2003). Different people from different functions are using the type of FMEA related to their purpose. As a result, the analysis and setting of priority becomes complicated, as each function has different priorities (Kmenta et al., 2003). In addition, a continuity of capturing and rectifying failures among different functions becomes almost impossible (Breiing and Kunz, 2002).

Another drawback of using FMEA in the prioritising of failures is based on the Risk Priority Number or RPN (Puente et al., 2001; Sankar and Prabhu, 2001). The highest RPN (Severity*Occurrence*Detection = RPN) is given priority for corrective action. However, the equation of different effect values for Severity, Occurrence and Detection does not reflect the potential risk, and not proportionate, could result in,

1. having the same RPN, for example in three instances, when 9*3*2 = 54, 2*3*9 = 54, or 3*9*2 = 54, the risk would nevertheless be completely different between the three RPNs,
2. having different RPN, for example, in two instances, when 9*3*2 = 54, and 4*5*6 = 120, the latter, with moderate RPN, is nevertheless given priority over the former with low RPN but high severity/detection and low occurrence.

The RPN is an oversimplification (Sankar and Prabhu, 2001), time-consuming assessment (Kmenta et al., 2003), and requires a substantial number of samples for the RPN to be valid, which is not possible in pre-production.

2.5.3.2 Deficiency in SSR

As discussed in Section 2.4.4.2, non-conformances discovered during product validation are commonly prioritised, simply based on three levels of severity, namely *Critical, Major* and *Minor* (Winchell, 1996; Ghinato, 1998; Kelly and Shepard, undated). Companies customised the three levels of non-conformances according to their preferences, for example representation by colour, alphabet, numbers, simple Go/No-go (Kochhar and Williams, 2001), or Good/No-good. The decision on how to describe non-conformances depends on the perception, experience and discretion of the senior member in the company. The major drawback with this qualitative approach is inconsistency in decision and control of non-conformances when different people and circumstances exist. Furthermore, this is not a quantifiable technique for empirical analysis and problem solving. In this context, priorities should:

1. reflect the seriousness of non-conformance,
2. be quantifiable to facilitate analysis and decision making,
3. be based on common understanding and interpretation of non-conformances,
4. be reasonably uncomplicated to deploy during validation in pre-production.

Although the priority methods discussed above facilitate the product validation process, problems in the control of non-conformances still persist. Hence, controlling non-conformances is pertinent to pre-production and this is another key area explored in this research.

2.6 CONCLUSION

As described above, quality is imperative for companies to be successful and competitive. Conformances to customer requirements have pushed companies to spend substantially to deliver quality products. However, to ensure quality is not an easy task. Rapid advances in product and corresponding technologies have made quality deliverables vulnerable to complexity, variation, and mistakes. As a consequence, products are prone to quality deficiencies and non-conformances. Product non-conformance is seen as one of the major factors that reduce company revenue, where

the implications are reflected in company financial performance. In a typical manufacturing company, non-conformances are identified at every stage of the product development process. However, the pre-production process is of major importance, since this is the last stage of review before the product is released for full production and subsequently to the customer.

Product non-conformance can be understood by recognising and drawing together holistically all matters that result in the deviation from specification and loss in quality. Mistakes are seen as the major source of non-conformances, and have to be identified and controlled. The literature survey shows there is a lack of research in identification and control of product non-conformance in pre-production. The current methods to identify and control non-conformances have some limitations due to the constraints surrounding pre-production. However, the understanding of mistakes and how to control non-conformances needs to be expanded. This can be achieved with a new perspective of understanding and enhancing the existing methods of control of non-conformances.

The next chapter presents an investigation in a multinational company which designs and manufactures consumer electronic products. The investigation addresses the issue of product non-conformance in pre-production as a consequence of mistakes.

CHAPTER 3

INDUSTRIAL EVIDENCE OF NON-CONFORMANCES IN PRE-PRODUCTION

3.1 INTRODUCTION

This chapter describes the understanding of critical aspects in the identification and control of non-conformances within the consumer electronic product industry. Product non-conformance evident in a multinational design and manufacture company has been investigated, illustrated and presented, which provides the justification for this research.

This chapter is structured as follows. Section 3.2 overviews the case company, its products, the pre-production operation, and the product validation process. Section 3.3 illustrates non-conformances identified during pre-production in the company. Section 3.4 then illustrates three cases of non-conformances identified during validation. Section 3.5 analyses the three cases comprehensively. Section 3.6 explains the outcome of the investigation of industrial non-conformances. Section 3.7 concludes this chapter.

This chapter establishes the key aspects which influence the development of research ideas which are presented in Chapters 4 and 5.

3.2 OVERVIEW OF INDUSTRIAL PRODUCT NON-CONFORMANCE

Similar to case study research, the industrial investigation carried out in this research delivers an analytical generalisation, as opposed to surveys, which produce a statistical generalisation. The aim of analytical study is to investigate a specific phenomenon that contributes to a problem. Hence, a small number of cases or problems are sufficient rather than compiling large numbers (Yin, 1994). This thesis illustrates and presents ten evidence of non-conformances of consumer electronic product, and analyses three of

them pertaining to 'what' are non-conformances and 'how' they exist during product validation in a multinational company. For the reason of confidentiality, the identity of the company is kept anonymous.

3.2.1 Company, Product and Pre-production Operation

The investigation is an assembly plant of a multinational company producing consumer electronic products in Malaysia. The author worked in the company in pre-production as a Product Validation Officer. The assembly plant is one of many located world-wide, with the head office and development centre (DC) in Japan, as shown in Figure 3-1. The company designs and produces two types of consumer audio products, the 'separate systems' (CD players and cassette player/recorder, tuner, receiver, amplifier) and the 'complete systems' (Hi-fi, Midi and Micro System). The products assembled are mostly derivative for high volume production. New and improved products are introduced quarterly for various markets around the world. The volume of production is between 100,000 to 250,000 units per batch.

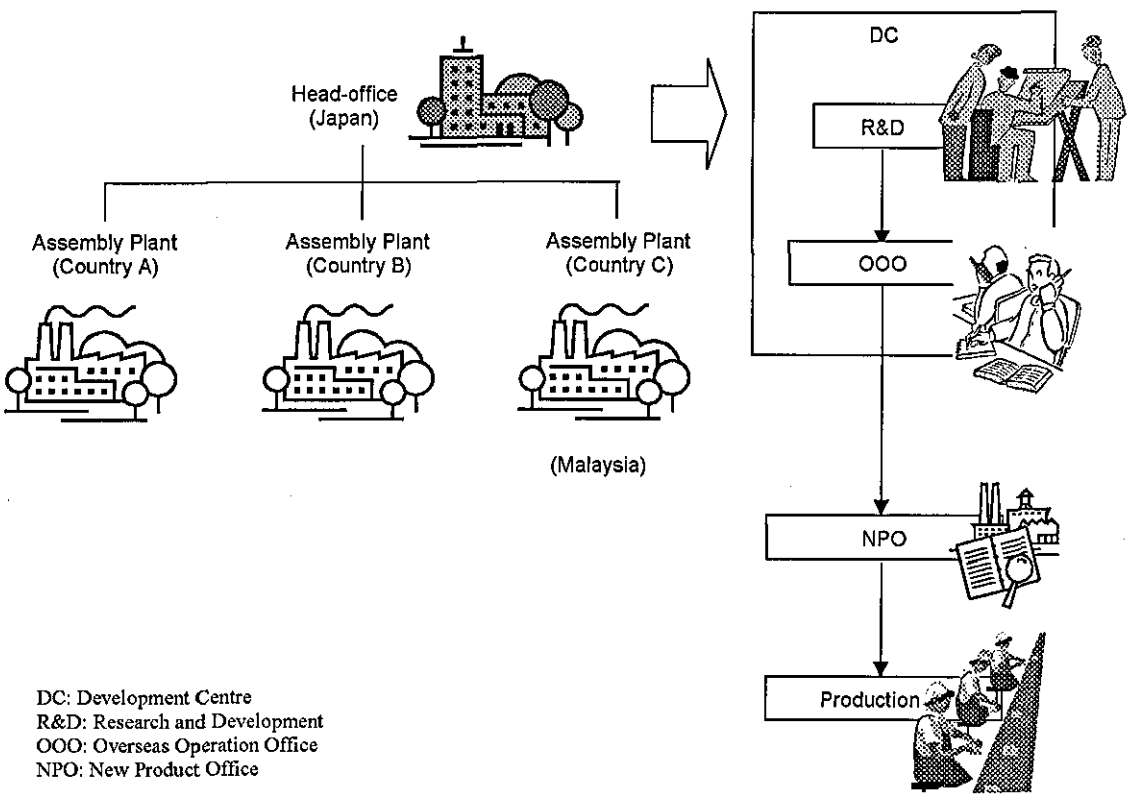


Figure 3-1 Head office and assembly plants of company

The pre-production function exists in every assembly plant, designated as New Product Office (NPO). The NPO operates with a small number of personnel whose main task is to validate products and facilitate the assembly plant in production and troubleshooting.

New products to undergo validation by inspection and testing are delivered from the DC through the Overseas Operation Office (OOO) and received by the NPO. The products are delivered in a batch of 5 to 7 units as 'finished products' between three to four weeks before full production. The tight schedule is seen as a major constraint for a complete and detailed inspection. Products are validated by the three key functions – NPO, Production, and Quality Assurance. Validation results are scrutinised, rectified where necessary, and verified prior to full production.

3.2.2 Product Validation Process

The company's product validation process model is shown in Figure 3-2. Products are designed and assembled by the DC, while trial-run products are assembled by the Production department. Validation is conducted by checking the products against the specification and quality requirement. Among the validation considerations are the reliability, aesthetics, the assemblies, and ISO Standards' compliance. Products are validated by inspection, testing, computer-based simulation and experience.

There are two outcomes from the validation: (i) product passes validation with either full conformance or conditional/compromised non-conformance, and/or (ii) product fails validation for severe and uncompromised non-conformance. Figure 3-3 depicts the company's product validation process flow diagram in general.

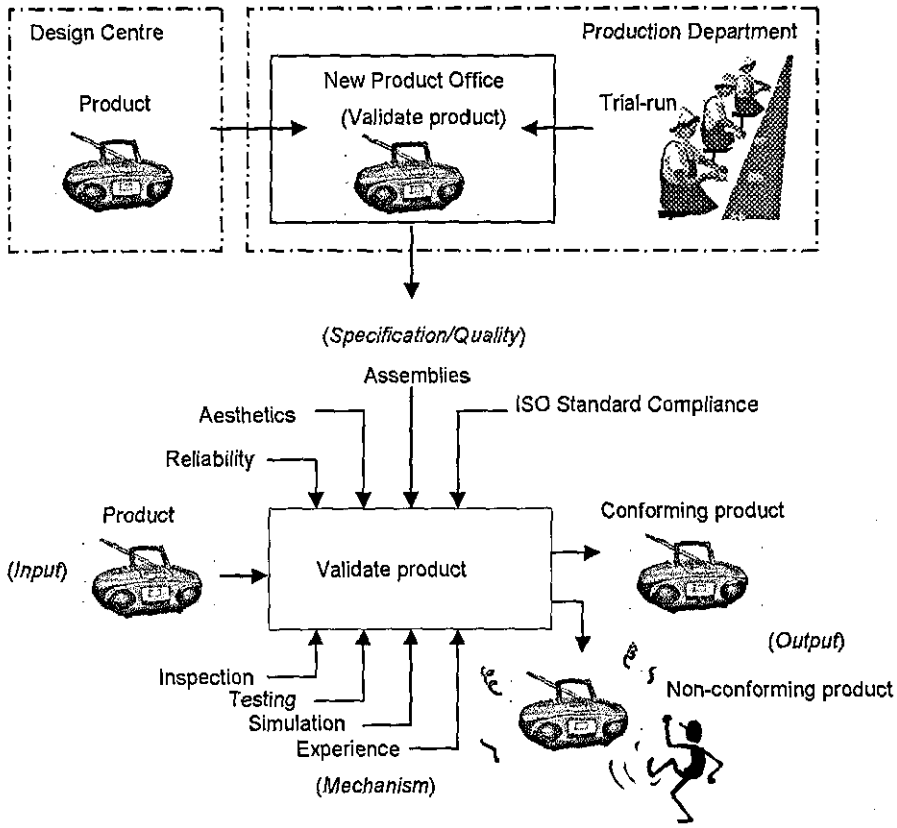


Figure 3-2 Company's product validation model

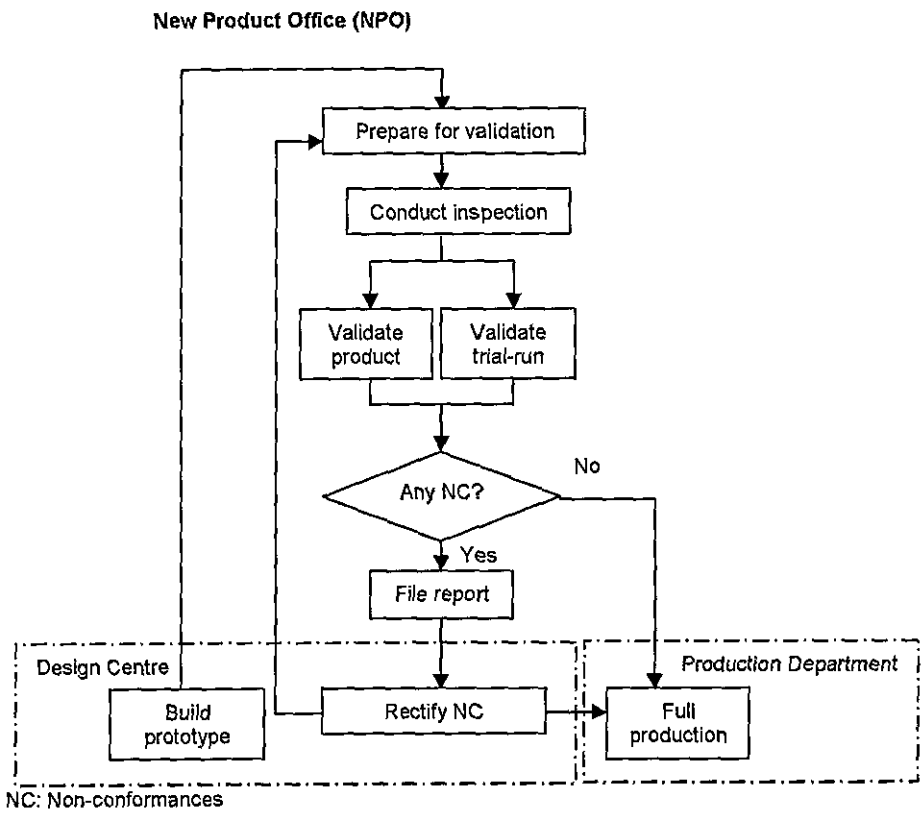


Figure 3-3 Company's product validation process flowchart

3.2.3 Inspection

Products are inspected in two phases: out-of-box inspection, and trial-run inspection, as shown in Figure 3-4:

Phase 1 - Out-of-box inspection.

The out-of-box inspection focuses on (i) the functionality, aesthetics, and the product's quality as perceived by customers, and (ii) the internal and external configuration as perceived by the production. This is done by checking and comparing the products against the specification and requirements. Inspection starts with a complete customer set, which is then dismantled and reassembled correctly to check the parts/components, and assembly arrangement.

Phase 2 - Trial-run inspection.

The trial-run inspection focuses on the ease and speed in assembly process, and the correctness of parts/components as they should be in the production lines. Parts/components are assembled on the actual assembly lines by the production operators. Inspection begins from the printed circuit board (PCB) assemblies through to the final packing.

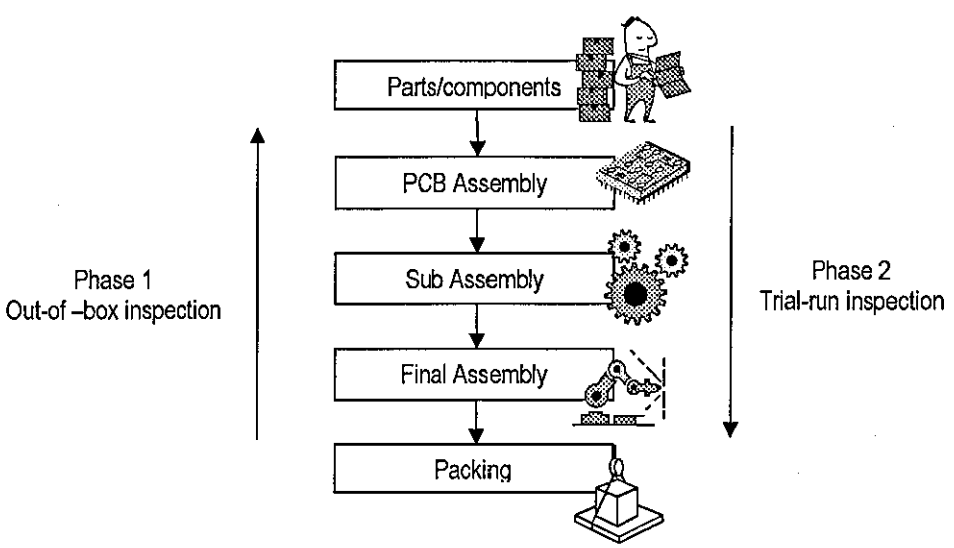


Figure 3-4 Company's two-phase/two-way product inspection

Figure 3-5 depicts the inspection activity sequence to identify non-conformances throughout the validation process. The two-phase inspection is an activity corresponding to the two-way validation process. The inspection starts after the NPO receives the products from the DC complete with their documentation. The NPO prepares for an inspection briefing meeting with the validation team. The meeting is to ensure that the product and documentation are complete and distributed to the inspectors, and that a trial-run is arranged with the production department.

In inspecting out-of-box, the product's functionality, aesthetics, and the product's quality are studied and checked as a complete product, as perceived by the customer. Then products are dismantled and reassembled according to the work instructions to inspect the parts/components and the assembly configuration. In inspecting the trial-run, parts and components are assembled in the production lines and five to ten sets of products are assembled according to the assembly drawings and work instructions. Every assembly progression is inspected from receiving parts/components up to packing the completed products.

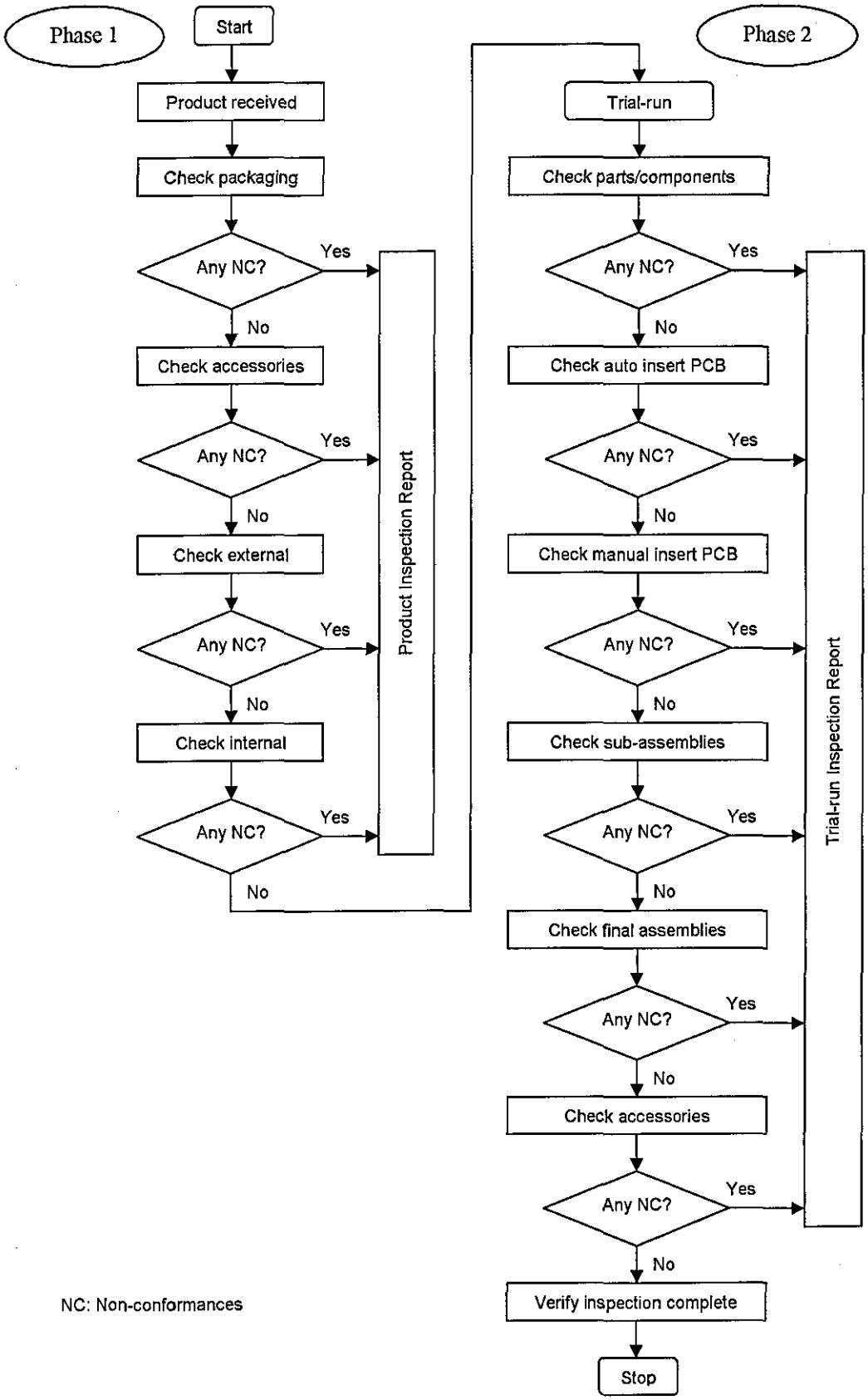


Figure 3-5 Company's inspection activity sequence flowchart

3.2.4 Outcome of Validation

The validation results are based simply on 'Good' or 'No-good' (NG). Good means the product conforms to the specification and quality is satisfied, as shown in the inspection checklist, drawings and other related documentation, while NG means non-conformances. The grey condition, when the product is either Good or NG, depends on the judgement of the validation team and senior manager, for example the colour of the company's logo on the front panel is slightly different from standard.

Products are qualified for full-scale production with two criteria, (i) products conforming to all specifications and fulfilling quality requirements, and (ii) compromised non-conformances/NG products, but with temporary or alternative solutions. Products failing validation are the uncompromised non-conformances/NG. The latter are reported to the DC to rectify. The rectified or revised products are sent to the NPO for re-validation, and the process is reiterated until the product qualifies for full production.

In summary, the following key characteristics have been identified in the company's pre-production operation:

- Product validation plays a major role in determining whether a product qualifies for full production.
- Validation process is constrained by too few products within a short duration for a rigorous assessment.

Hence, it can be seen that the main driver to conduct product validation is to ensure the integrity of products with specification, quality and producibility, whilst avoiding the consequences of non-conformances.

3.3 PRODUCT NON-CONFORMANCE IN PRE-PRODUCTION

Pre-production is a sensitive area in this company and all others in the design and manufacturing industry. Access into the facility is very restricted and most of the information and activities are kept confidential. Because of confidentiality, detailed reports and the statistics of non-conformances of both phases of inspection are not permitted to be disclosed. These include data on the inspections and tests results related to non-conformances of the latest products under validation, and data on acceptable non-conformances released for production. Therefore, limited data from obsolete products were permitted for this study. For this reason, ten evidences of non-conformances are presented in this chapter.

During the two-phase validations, various non-conformances are identified as manifestations of deviation from specification, abnormalities, and poor quality. The non-conformances are manifested in many aspects, for example the documentation (especially drawings and bill of materials), the materials, parts and components, the assembly arrangements, the internal and external features, and the functionality.

As described in Chapter 2, mistakes are the major source of non-conformances. The consequences of mistakes which result in non-conformances (Hinckley, 2001) identified during product validation are described in the following paragraphs. For the purpose of demonstrating the state of non-conformance, the figures and diagrams presented correspond to the actual and similar events occurring in the company.

3.3.1 Mistakes Identified During Inspection

3.3.1.1 Omitted information

Information essential for the correct execution of a process or operation is not available or has never been prepared. For example, part names for assembling a component were not given in the assembly drawings but only part number, as shown in Figure 3-6. As operators are used to identifying parts by names, parts and components were mixed or fixed with the wrong part during trial-run assembly.

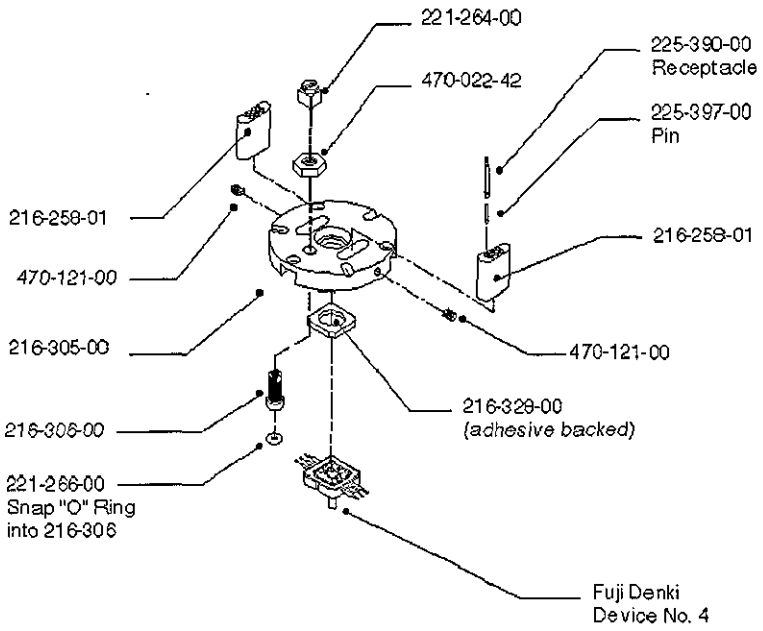


Figure 3-6 Omitted part name in assembly drawing

3.3.1.2 Ambiguous information

Errors in understanding correct information. For example, one of the most common mistakes is attaching the part wrongly. As shown in Figure 3-7, the working instruction is confusing because the harness (a) and the two jacks (b) are illustrated differently, although the correct position is already stated in (a).

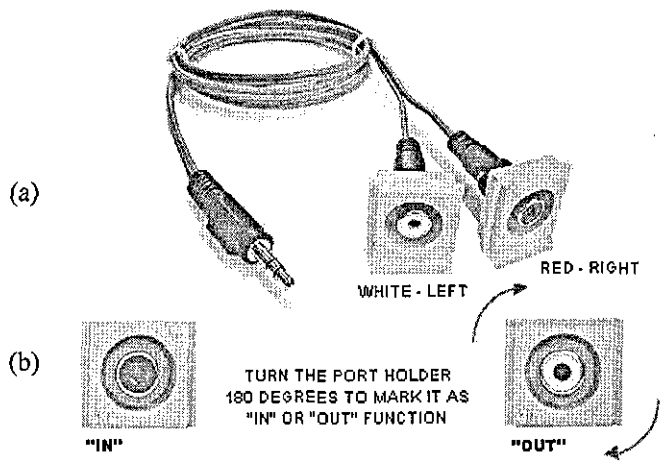


Figure 3-7 Two contrasting illustrations of part

3.3.1.3 Incorrect information

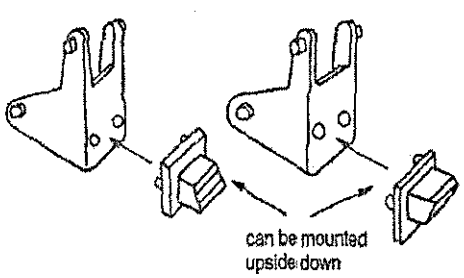
Information provided is incorrect. For example while assembling the product in Phase 1, the inspector followed the assembly procedure based on the working drawings that was read correctly, but some parts of the drawings were incorrect. This condition happens when the latest engineering change orders are not available.

3.3.1.4 Inadequate warning

A warning is sent or readily available, but the method of warning is not adequate to attract or hold the tester's attention. For example, the warning to use a soft cloth to protect the LCD panel during testing was not adequately given. Although the LCD was covered with a thin plastic film, it was insufficient to protect from scratching. The warning was written only in the remarks section, and not highlighted on the assembly illustration in the test sheet.

3.3.1.5 Wrong orientation

A part is inserted in the correct location, but the part has the wrong orientation. For example, during the sub-assembly trial run, it was found that the eject buttons can be mounted in either direction, as shown in Figure 3-8, hence correct instruction is critical, especially when running full production.



Source: Nikkan Kogyo Shimbun (1988).

Figure 3-8 Button which can be assembled wrongly

3.3.1.6 Wrong part

A part is selected, but it is the wrong part. For example, the colour of the LCD display, as shown in Figure 3-9, varies according to the different versions of the same model. For the Asian market, the products to be fixed with an amber LCD display were mixed with the EU version which requires a bright white LCD display.

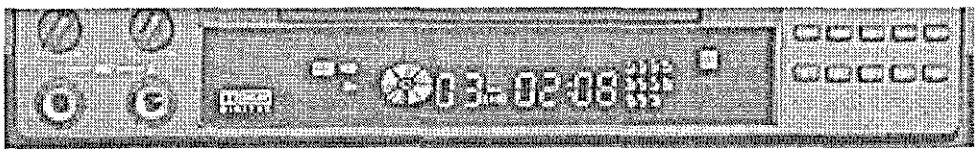


Figure 3-9 White LCD display

3.3.1.7 Omitted part

A missing part resulting from failure to comply with correct product requirement. Often recurring non-conformances are of this nature due to the similarity of many product versions. For example, a label on the rear panel of a product was found missing during inspection, as shown in Figure 3-10. Most products use the same panel but with a different label requirement. Further explanation regarding this problem is given in Section 3.4.1.

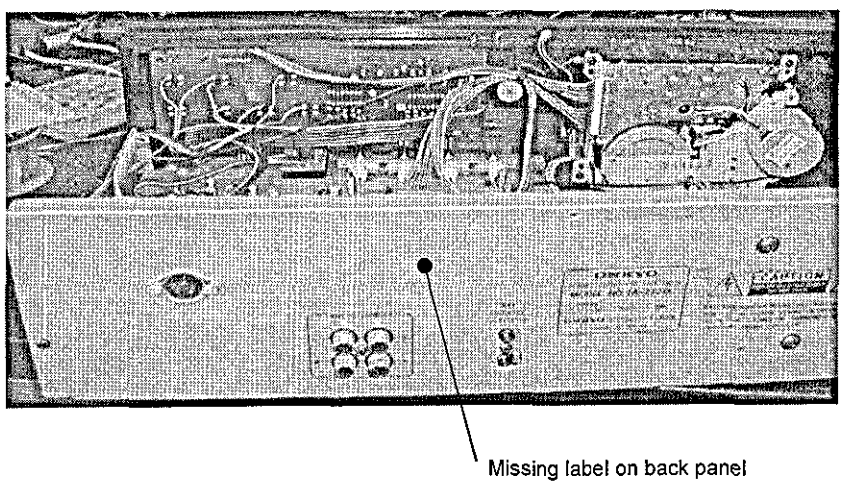


Figure 3-10 Missing label

3.3.1.8 Omitted operation

Failure to perform a required operation. For example, a pad to protect an electronic component from contact with the product's chassis was omitted, although the PCB was functioning. Figure 3-11 shows the electronic components protected correctly with pads.

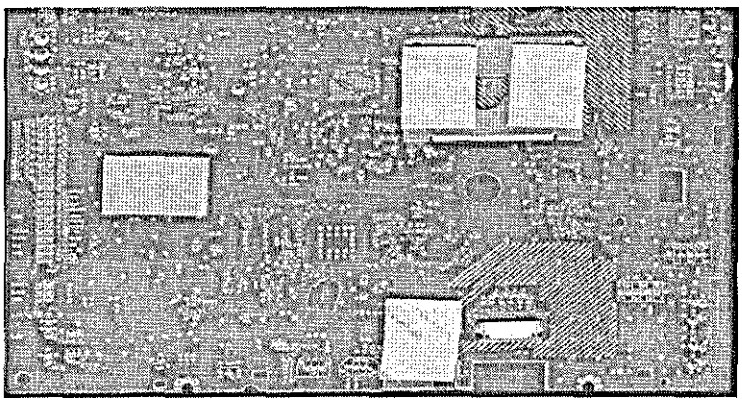


Figure 3-11 Protection pads on electronic components

3.3.1.9 Defective material

The material entering a process is defective, or inadequate for the intended function, process, or purpose. For example, the two cassette lids did not open simultaneously when both eject buttons were pressed, as shown in Figure 3-12. One of the lids was suspected to be out of dimension because the lid touched the opening frame, leaving no gap. Further explanation regarding this problem is given in Section 3.4.3.

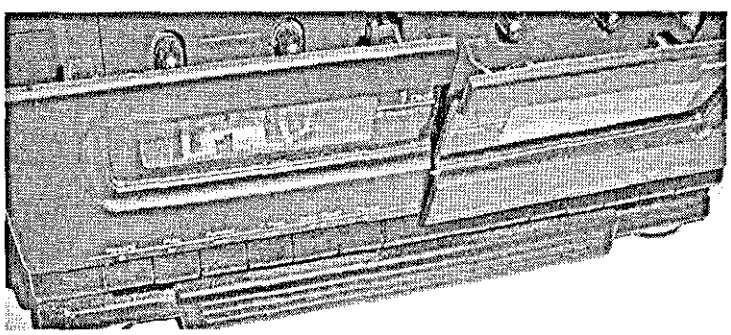


Figure 3-12 Two cassette lids open at different pace

All non-conformances described above are logged in the inspection report for analysis to determine the severity and priority, and whether the product is flagged either Go or No-Go for subsequent process. Other non-conformances which result as consequences of other mistakes are also identified during product validation.

In summary, the evidence presented above exhibit a range of non-conformances as the consequences of mistakes which the researcher came across during product validation in the company. In analysing these non-conformances, the researcher concluded that non-conformances are manifested as physical and touchable variables, which result in abnormalities, diversion from specification, and loss of quality. In addition, non-conformances can be classified into three generic classes:

(i) Information (cases 3.3.1.1, 3.3.1.2, 3.3.1.3 and 3.3.1.4)
(ii) Process (cases 3.3.1.5, 3.3.1.6, 3.3.1.7 and 3.3.1.8)
(iii) Parts/components (case 3.3.1.9)

An elaboration of this classification is given in Section 3.5. The next section describes the three evidence of non-conformances identified during both Phases 1 and 2 inspections, followed by the analysis of the evidences. The analysis has led the researcher to discover a new perspective in classifying non-conformances in pre-production.

3.4 ILLUSTRATIVE EVIDENCE OF NON-CONFORMING PRODUCT

This section describes three cases of non-conformances identified during validation. All the cases demonstrated a common cause of non-conformance, which are mistakes. These cases are carefully selected to represent three different aspects of non-conformances:

Case 1 – related to product information non-conformance
Case 2 – related to product process non-conformance
Case 3 – related to product parts/components non-conformance

The non-conforming product is a consumer audio product – a midi player, consisting of CD player, radio, and twin cassette player/recorder with detached speakers, as shown in Figure 3-13.

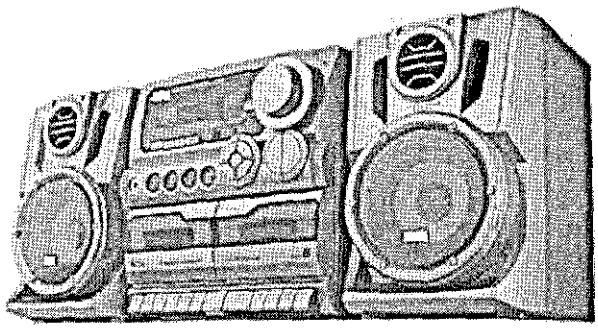


Figure 3-13 A midi player

3.4.1 Case 1: Non-conforming Product Safety

The company assembles various versions of similar midi players for different markets and countries. Some markets require a product to be certified to specific quality and safety standards and requirements. Special organisations controlling standards award compliance certification to companies that produce products which meet the standard. For example, products marketed to northern America are required to obtain the UL (Underwriters Laboratory) and CSA (Canadian Standards Association) certification, while products marketed to the European Community requires the CE (Conformité Européenne or European Conformity) certification. Companies receiving the certification are required to label their products with the official certification emblem. Figure 3-14 shows some of the certification emblems used on products for different countries. These confirm that quality and safety are assured in accordance with the standards and requirements. The label of the emblems is pasted or imprinted on the back and bottom panels of the midi player.

Figure 3-14 Common quality and safety certification emblems.

Other information such as notices, messages, warning signs and special instruction are also pasted or imprinted on the product. For example, the power supply information requirement for the British market is 250V, while for the American market it is 110V; therefore, an appropriate power supply sign is required to be attached to the product.

Missing labels or messages were identified during validation, as shown in Figure 3-15. Ironically, the labels and messages are among some items in the checklist that are given priority in inspection. Missing items are classified as 'No Good', inspection is halted, and New Product Office immediately contacts the Development Centre for clarification.

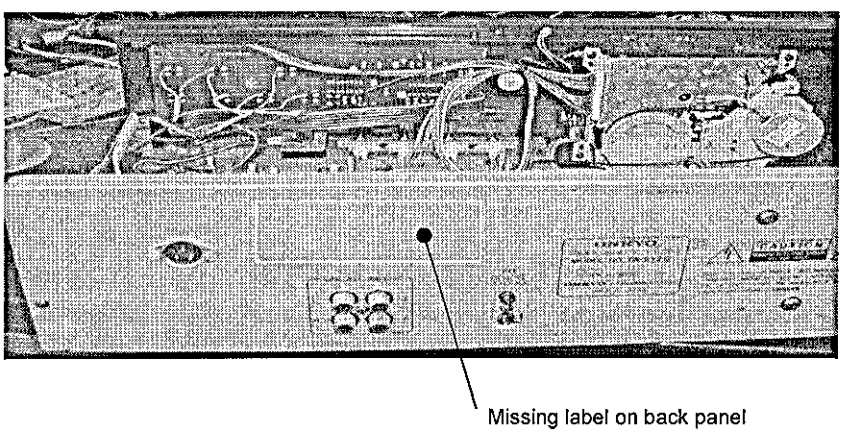


Figure 3-15 Missing label and practical solution.

One practical way to deal with this problem is by imprinting a permanent marking for placing the labels or stickers on the back panel, for example the white box as shown in Figure 3-15. Missing labels and messages can thus be identified immediately on the panel. This is significantly useful during high volume production.

3.4.2 Case 2: Non-conforming Printed Circuit Boards

In trial-run, the inspection includes checking the Printed Circuit Boards (PCB) which contain hundreds and thousands of minute electronic components (Figure 3-16). The components are of different types such as radial, axial, surface mountable, integrated circuit (ICs/chips), and large components such as harnesses, transformers, and heat-sinks. Large components are manually inserted, while the smaller components are inserted into the PCB automatically, using machines.

A blank PCB contains an imprinted component layout on one surface, embedded circuit on another surface, and thousands of cavities where the components are inserted. Identification of component on a PCB is by referring to the component layout on the PCB, the PCB drawings, and BOM. There are four types of PCBs - main-board, tuner card, sound card, and amplifier board. As new and improved functionalities are added to a product, the PCBs also undergo upgrading, where components are replaced, added or removed from the PCB.

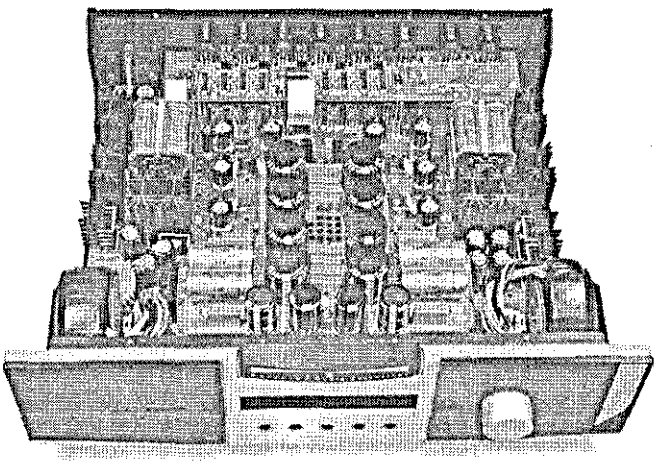


Figure 3-16 Assembled PCB

One of the inspection tasks is to count the number of components and identify their location to ensure similarity with the PCB list and drawings. Documents are checked for incorrect and omitted information, while the components on the PCB may be defective, missing, or wrongly located. Often the numbers are mismatching and require rechecking. The problem is that to identify just one location of a component is a time-consuming and tedious task. As there are four types of board to check, and a variety of products to validate, inspection is slow, and inadvertent mistakes are inevitable. Nothing is done to improve this practice, as everybody is complacent, with visual browsing on the surface of the PCB, no matter how long it takes.

3.4.3 Case 3: Non-conforming Cassette Player Lids

One of the 'out-of-box' inspections is to check for the functionality of the twin cassette players. An abnormality was discovered when the two front-loading cassette lids did not open simultaneously on pressing both eject buttons, as shown in Figure 3-17.

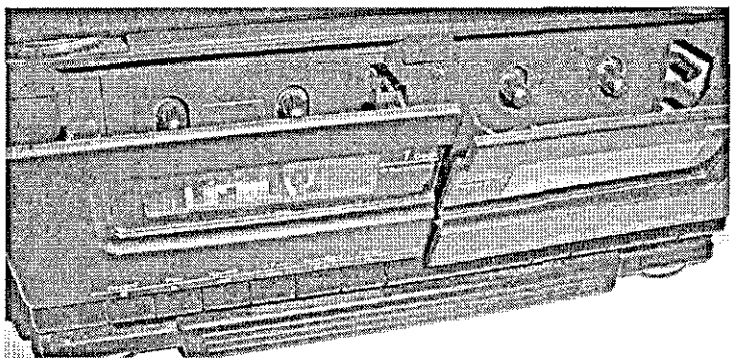


Figure 3-17 Cassette lids not opening simultaneously

This was an unprecedented problem, because checking of the lids is not stated in the inspection checklist. Investigation was commenced immediately to find the cause. The assumptions were that either the gear fitted to one of the lids was fastened too tightly to the housing, or blockage was due to foreign materials (e.g. dust residing between the gears), wrong part (spring, cassette lid, lid frame), or wrong method of fitting of the lids.

The product was dismantled, grease was applied to the gear, and dust was blown away. However, after conducting repetitive tests, the problem persisted. Other possibilities were investigated which were the parts/components and the assembly method. These possibilities were checked against the specification and drawings.

The NPO, DC and Production assessed the problem and classified the problem as conditional or compromise NG. Due to tight production and shipment schedules, a decision was made to go ahead with production, but with a temporary solution (applying grease to the cassette doors) while the problem was rectified. The production was for the initial batch only. From the assessment, they concluded that the problem was overlooked at the DC.

It is concluded that from the cases presented above, variables of deviance from specification and quality discrepancy manifested as the consequence of mistakes led to product non-conformance. Inadvertent mistakes are inevitable, and non-conformances are often overlooked in all development progression and assessment activities. Hence it is critical to identify non-conformances and the aspects that contribute to them, so that the problems can be minimised and controlled prior to production.

3.5 ANALYSING EVIDENCE OF NON-CONFORMANCES

3.5.1 Factors Contributing to Non-conformances

Case 1: Non-conforming product safety – Information non-conformance.

Product safety label not attached to the back panel is the product information requirement either not needed for a particular product or inadvertently omitted. The non-conformances are identified as omitted part (the safety label), and omitted information (relating to product safety). This condition is obviously due to human mistakes, when under pressure from tight schedules and market differentiation for a similar product model, the requirement for the safety label has been overlooked. Ironically, this is an essential information compliance requirement regarding product safety, and is a priority in reviews and inspection. However, this problem can be overcome using appropriate technique such a mistake-proofing (Shingo, 1986), as suggested in Section 3.3.2.

Case 2: Non-conforming printed circuit board – Process non-conformance.

Mistakes in identifying thousand of components on a PCB occur at every stage, from design through to pre-production and production. This situation suggests that validation should consider the aspects of easing the inspection and production process to avoid mistakes such as counting errors or omitted components. This can be achieved by imprinting thin horizontal and vertical lines on the PCB and drawings which correspond to grid lines, as shown in Figure 3-18. Components can be easily identified by the grids, as in maps, on both surfaces of the PCB and drawings, consequently reducing the time for inspection. The process of identifying and inserting components manually is easier,

as the component locations are quickly known. Hence, non-conformances from missing components or undetected components will be reduced.

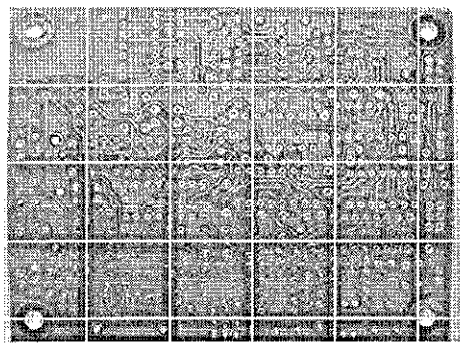


Figure 3-18 Imprinted grid lines on both surfaces of PCB

Case 3: Non-conforming cassette player lids – Parts/components non-conformance.
Variables such as foreign material, gear, spring, cassette player lids, lid frame, inspection check list, and assembly methods are elements where non-conformances occur, as shown in Figure 3-19.

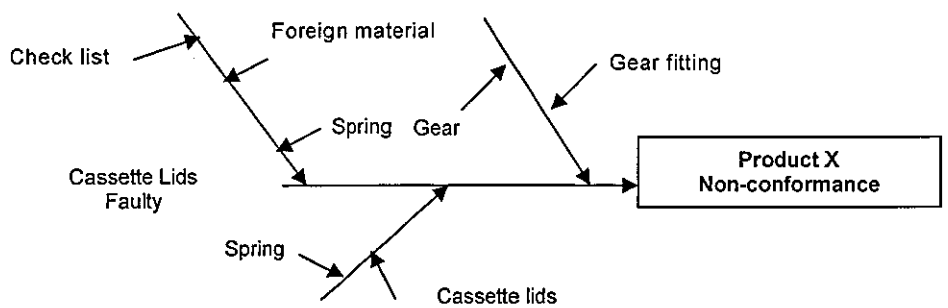


Figure 3-19 Elements contributing to non-conformances

There are also tangible factors, such as mis-adjustment, defective material, omitted information, wrong parts, and wrong operation, which cause non-conformances. How are these two aspects linked? A cause and effect diagram in Figure 3-20 presents the correlation between the tangible and intangible factors which contribute to non-conformances. For example, the gear (a tangible factor) was misadjusted (intangible) when tightening screws with tight torque or not fitting the gear according to the pre-determined sequence (wrong operation) are the most likely causes of the faulty lid.

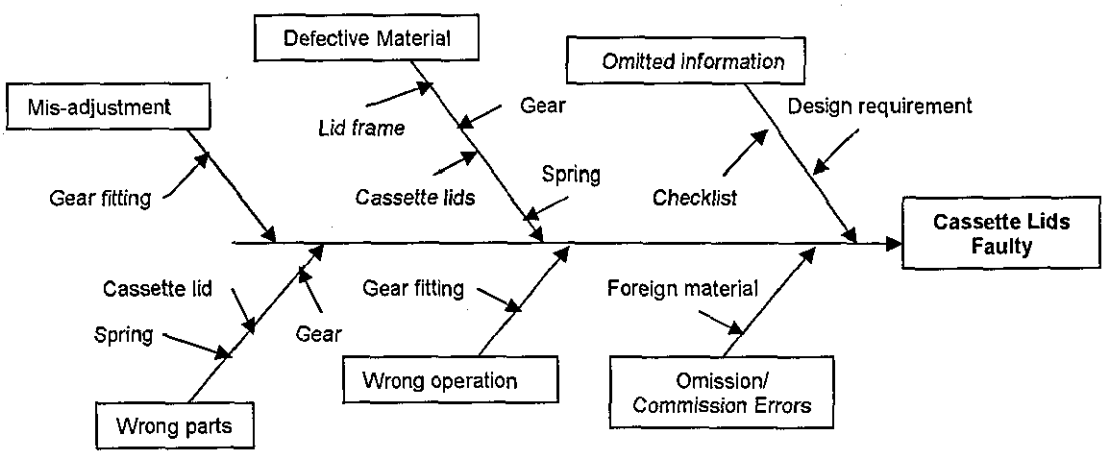


Figure 3-20 Elements and tangible factors causing faulty cassette lid

Further representation of the correlation between the two factors is presented in the correlation matrix, as shown in Table 3-1. Mis-adjustment and wrong operation in fitting the gear have high probability or strong connection for causing the faulty lid.

Table 3-1 Correlation between elements and tangible factors

⊙ Strong Connection O Connection		Tangible Factors					
	Elements	Defective material	Omitted Information	Misadjust	Prohibited Act	Wrong Operation	Wrong Parts
Cassette Lids Faulty	Gear fitting			⊙		⊙	
	Foreign material				O		
	Gear	⊙					O
	Spring	⊙					O
	Cassette lids	⊙					O
	Lid frame	O					
	Check list		⊙				
	Requirement		⊙				

The three cases described above have demonstrated that the factors contributing to non-conformances are variables from *tangible* and *intangible factors which are the consequence of mistakes*, as listed:

- in case 1, omitted part, omitted information
- in case 2, counting errors, omitted component
- in case 3, mis-adjustment, defective material, omitted information

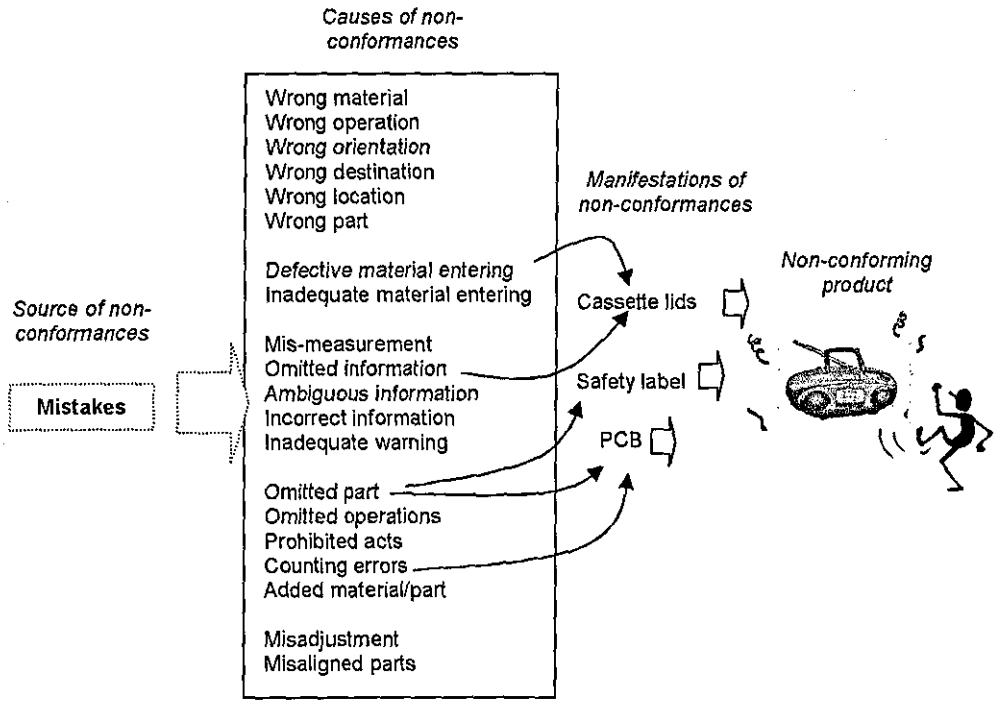


Figure 3-21 Source, causes and manifestation of product non-conformance

Other consequences of mistakes (Hinckley, 2001) are shown in Figure 3-21. These are the mistakes commonly identified in pre-production manifested either deliberately or inadvertently; however, the main source is mistakes. Therefore, non-conformances should be emphasised appropriately in the inspection checklist, and the checklist updated continuously when new non-conformances are identified.

3.5.2 Determining Type of Non-conformances

From the researcher's observation, the products under validation are characterised by the product Information, Process and Parts/Components. The product information is related to the standards, specifications, bill-of-materials, instruction and drawings. The product process is related to the PCB assemblies, sub-assemblies, final assemblies and packaging. The product parts/components are related to the packaging materials, accessories, and functional parts which are mechanical, electronic and electrical.

It was found that the product's characteristics also are the main considerations in product validation. Therefore, it can be concluded that there are three validation

considerations which correspond to the product characteristics - Information, Process and Parts/Components. The details of the validation considerations are listed in Tables 3-2, 3-3 and 3-4. These considerations have not been defined and structured appropriately in the case company, as described in Section 3.2.2.

Table 3-2 List of validation considerations related to Information

Particulars	*Information Description*
Drawings	▪ Complete set of the most recently approved assembly, detail and working drawings. ▪ Information on drawings identification, for example drawing number, title, page number, dimensions, notes, amendments, symbols, conventions, etc.
Bill-of-Materials (BOM)	▪ Most recent approved documents with complete list of mechanical and electronic parts and components, and sub-assemblies.
Packaging	▪ Printed identifiable product information, for example labels, graphics, colour, languages, instructions, messages, numbers, characters on the carton boxes, plastic/paper wrappers and polystyrene-foams, bar-coded product information, etc. ▪ Safety information on carton boxes, plastic wrappers, and polystyrene foams, for example weight, size, handling orientation, stacking guides, safety messages and instructions, etc. ▪ Complete set of accessories printed materials. ▪ Instructions, manuals, booklets, warranty card, reply cards, for example for all accessories, with part name and part numbers, labelled, correct languages on printed materials.
Product Safety	▪ Assembled, sub-assembled parts, mechanical and electronic components are clearly labelled or imprinted with safety messages, warnings and instructions in compliance with safety standards and specifications.
External and Internal Panels	▪ Brand logo, model identification (name of model and unique number on stickers or imprinted); labelling for functions and features (for example power on-off, volume, left/right, etc.). ▪ Dismantling instructions, messages, warnings and instructions all around and inside the product.
Parts and Components	▪ To tally with detail and assembly drawings, for example dimensions, type of material, colour, etc.
Testing and Measurement	▪ Testing and measuring the electronic and electrical values as per specification and safety requirements. ▪ Quality and reliability testing and measurement, including information for packaging specification.

Table 3-3 List of validation considerations related to Process

Aspects	*Process Description*
PCB assemblies	▪ Both automated and manual insertions, for example new and additional components, components to be removed or replaced.
Sub-assemblies	▪ Sub-assembled parts, for example product modules, CD/cassette drivers, PCBs. ▪ Fitting of loose parts, for example bolts/nuts, plastic fasteners, joints, brackets, housings, washers, wiring, lids, bases, etc.
Final assemblies	▪ Fitting all sub-assembled parts and modules according to procedures, with special care.
Packaging	▪ Packing of items with packaging materials using appropriate methods, sequence and orientation of packaging. ▪ Instruments, tools, equipment, and handling. Attention will focus on the type of tools needed to assemble the product. Where necessary, jigs, gauges and fixtures will have to be supplied. Special requirements for tools, equipment, handling methods or even testing instruments are avoided as much as possible.

Table 3-4 List of validation considerations related to Parts/Components

Particulars	*Parts/Components Description*
Packaging configuration	▪ Carton boxes. ▪ Plastic wrappings for product and accessories. ▪ Polystyrene foam (protecting product). ▪ Packing seals and cushioning (bubble packs).
Accessories	▪ Complete set of printed materials, for example warranty cards, reply cards, manuals, instructions booklets. ▪ Complete set of accompanying items, for example remote controls, cables, loud-speakers, batteries, antenna, and other related items.
Product	▪ Physical and appearance. ▪ Casings (front panel, rear panel, base, lids, and battery lids), colour, materials, stickers, etc. ▪ Moving mechanism, for example buttons, CD trays, sliders, cassette decks, antenna, handles, knobs, and other parts. ▪ Cables and fittings, for example power supply, external antenna, speakers, microphone and headphones. ▪ Mechanical and electronic assemblies. ▪ Fittings, housings, brackets, fasteners, joints. ▪ PCBs (main board, tuner board, AV boards), LEDs, miniature components, wire harnesses, displays, motors, cables and wiring connections, etc.
Functionality	▪ Conditions and features as per requirement and working together with accessories.
Safety	▪ Visual, audible and tactile check on mechanical parts, for example sharp and pointed edges, loose assemblies, breakages, foreign materials, etc. ▪ Visual and audible inspection, and testing on wiring and cables insulations, labels, colour codes, warning signs, jacks and insertion, LEDs, etc.

As shown in Figure 3-22, the arrows pointing towards the product represent the product's characteristics, while the dotted arrows are the relationship between the three validation considerations. When inspecting one aspect, it is necessary to counter-inspect with the other aspects. Hence, products are validated for integrity among characteristics, as dictated by the specification and quality requirements.

Any deviation from specification and loss of quality identified in the product's characteristics during validation represents manifestation of non-conformances. For example, in Case 1 of non-conforming product safety, this is considered as failure to conform to the product's Information requirement on safety standards. In Case 2 of the PCB assembly, this is considered as the product's Process issue which has the potential to develop non-conformances. In Case 3 of faulty cassette lids, this is considered as failure to conform to the product's Parts/Components quality requirement.

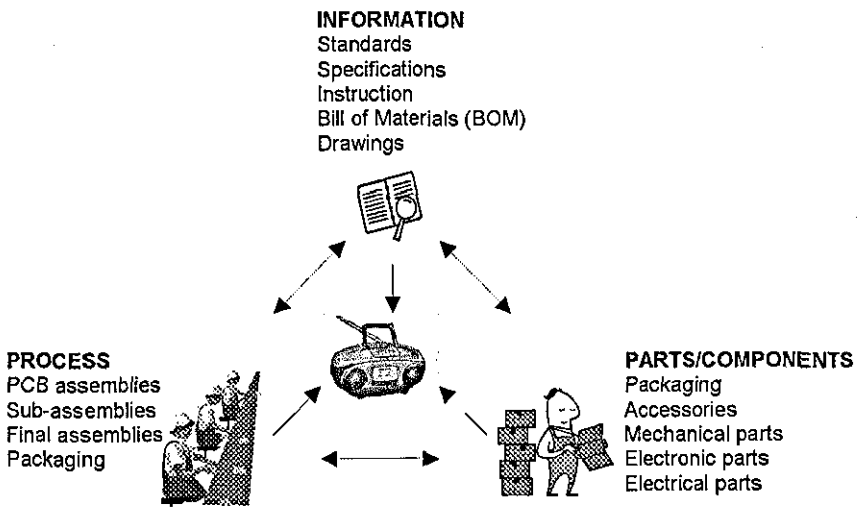


Figure 3-22 Product characteristic/validation considerations

3.6 IMPLICATION OF INDUSTRIAL INVESTIGATION

It is concluded that from the industrial investigation presented above, variable deviance from specification and quality discrepancies manifested as the consequence of mistakes either deliberately or inadvertently, led to product non-conformance. Non-conformances are often overlooked in all development progression and assessment activities. Hence it is critical to identify non-conformances and where they are manifested prior to production, so that the consequences can be minimised and controlled.

The investigation also concludes that products under validation have three characteristics - Information, Process and Parts/Components. It has been shown that validation focuses on the items within these three product characteristics as the main considerations; hence identification of non-conformances should be directed on these items manifested in each characteristic. For this reason, non-conformances can be classified based on the product's characteristics/validation considerations.

The connection between these two aspects, mistakes and product characteristics is seen to be a significant and practical basis for the formulation of new non-conformance classification. Hence, the research suggests three classes of non-conformances:

1. Information non-conformances
2. Process non-conformances
3. Parts/components non-conformances

This conclusion contributes in the formulation of a new non-conformance classification, explained in Chapter 4.

3.7 CONCLUSION

The company where the researcher has worked has participated in this research. Since pre-production is a sensitive area in the company, only selected data on product non-conformance have been permitted for use in the thesis.

Non-conformances described in the three case studies above were identified during the two-phase product validation activities. The source of the non-conformances is mistakes which were made in the Development Centre. The product validation tends to be production-oriented, with the aim to verify that products are qualified for full-scale production and to prevent non-conformances from escaping into the assembly lines.

A structured and explicit approach to identify non-conformances is lacking in the company, as most of the inspection is carried out to identify only the tangible non-conformances. In addition, the company's approach to validating products is based on a simple classification, which is Good or No-good. This classification was found to be too vague and requires the experiential judgement of senior personnel before a decision is made. From the case studies, it was concluded that:

1. The manifestation of non-conformances is found to be the consequence of mistakes.
2. A holistic approach to identify and describe non-conformances is crucial. Subsequently, non-conformances are suggested to be grouped into three main classes: Information, Process and Parts/Components, in conjunction with the product characteristics.

3. In order to prevent non-conformances from escaping into production, an improvement to the validation process is needed in which the information and knowledge can be reused in dealing with product non-conformance in pre-production.

In the following chapter, the researcher introduces an improvement to the product validation process through novel approaches in identification and control of product non-conformance in pre-production.

CHAPTER 4

A NOVEL APPROACH TO IDENTIFY AND CONTROL PRODUCT NON-CONFORMANCE IN PRE-PRODUCTION

4.1 INTRODUCTION

This chapter presents a novel approach to address non-conformances and improved product validation in pre-production after establishes the key issues discussed in previous chapter.

This chapter is composed of Section 4.2 which introduces two key research ideas: (1) introduction of a new non-conformance classification to aid identification of product non-conformance, and (2) a method to aid controlling of non-conformances during product validation in pre-production.

The research ideas in the form of theoretical concepts presented in this chapter are deployed in product validation through a proposed validation workbook, which is formulated in Chapter 5.

4.2 DEVELOPING AN APPROACH TO IDENTIFY AND CONTROL PRODUCT NON-CONFORMANCE

To addresses the two research questions mentioned in Section 4.2.4, new approach to identify and control non-conformances, and consequently improve the product validation process in pre-production is presented. The following sections provide an overview of

1. Product-based Non-conformances Classification or PNC, a new classification of non-conformances used to identify the non-conformances in pre-production.

2. Non-conformances Consequence/Solution or NoCoS methodology, a method used to determine the severity of non-conformances and instigate the solution in the product validation process.

4.2.1 Modelling Product Validation Process in Pre-production

Figure 4-1 illustrates the product validation process in pre-production, incorporating the idea of identifying (PNC) and control (NoCoS) of non-conformances. This illustration is based on the IDEF0 activity modelling (Bal, 1998; Cheung and Bal, 1998; Dorador and Young, 2000). In this framework, the products to be validated are the prototype and trial-run product, simply known as the product. The product is validated against the specification and quality requirements. Non-conforming items are identified and classified by the Product-based Non-conformance Classification or PNC. Subsequently, the products are analysed and prioritised using the Non-conformances Consequence/Solution or NoCoS methodology.

The PNC and NoCoS enhance the product validation process in pre-production and facilitate decision making in the product development process. A step-by-step procedure to deploy both the PNC and NoCoS is formulated into the validation process described in a product validation workbook, explained in Chapter 5.

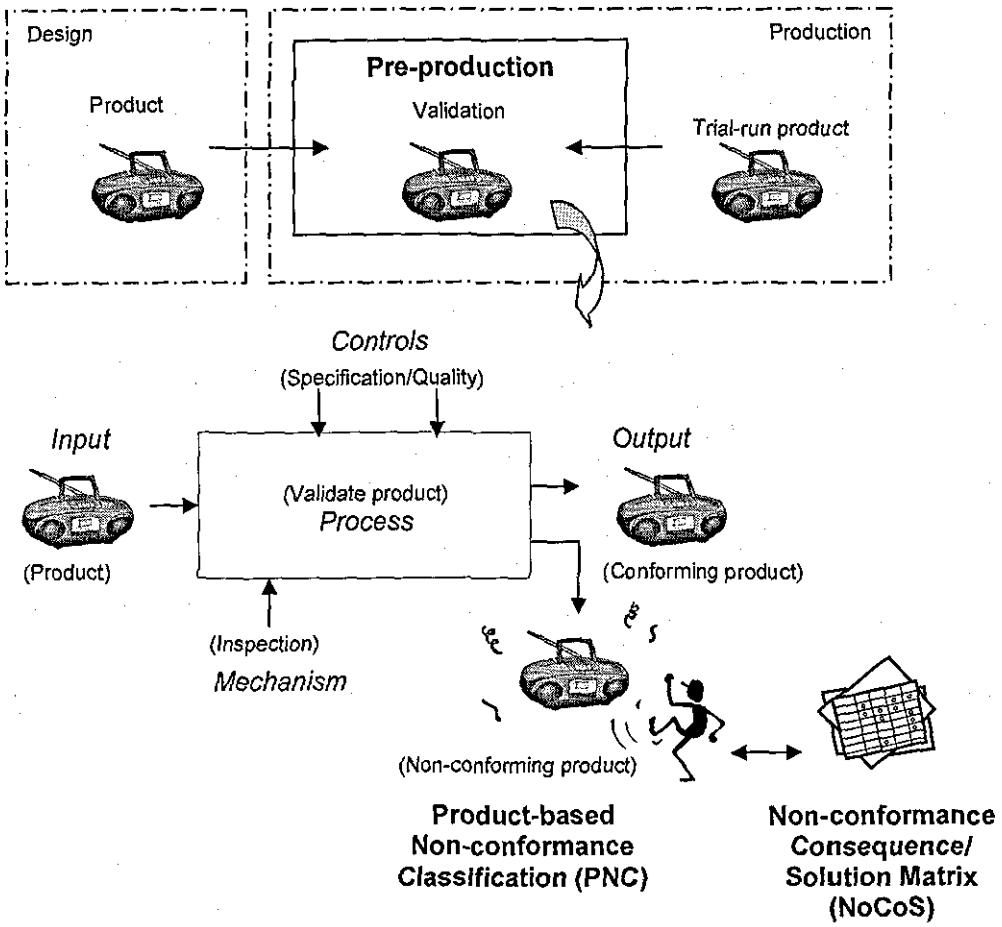


Figure 4-1 Product validation process framework

4.2.2 Product-based Non-conformance Classification - PNC

The elimination of non-conformances is difficult because no matter how good a method is used to prevent non-conformances, mistakes will recur (Shingo, 1986). However, non-conformances can be reduced and controlled (Hinckley, 1997, 2003). One way in pre-production is by identifying the non-conformances holistically, followed by deploying an extensive control method. The first research question is addressed in the following paragraph which introduces a new approach to identifying non-conformances in pre-production.

4.2.2.1 Product Characteristics

The new approach to product identification is based on the characteristic of the product under validation in pre-production. From the literature and industrial investigation, the

research has identified three interrelated characteristics of product in pre-production, as shown in Figure 4-2:

a. Information b. Process c. Parts/Components

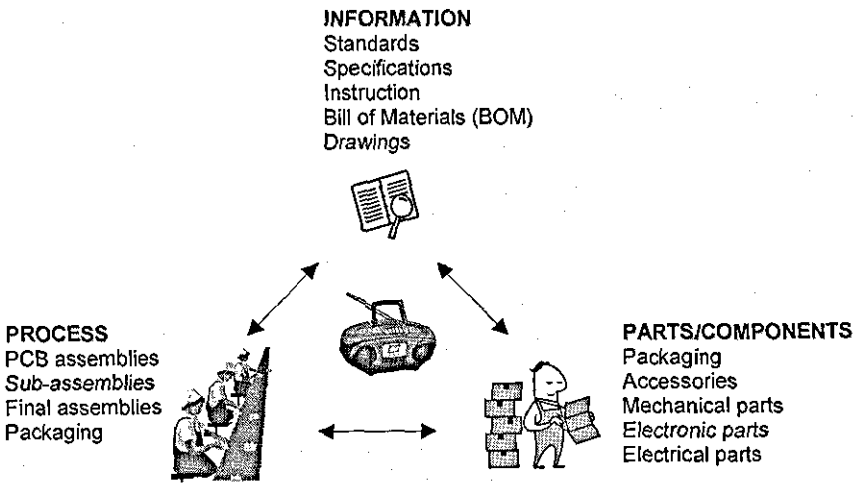


Figure 4-2 Three interrelated product characteristics in pre-production.

The pre-production product is accompanied with a complete set of control documents or *information.* These are technical documentation pertaining to the product and its assembly process. The documents, among others, are,

- specification and standards
- drawings
- bill-of-materials (BOM)
- procedures and instruction
- engineering change orders (ECO)

In the trial-run, the whole *assembly process* is looked into according to assembly information such as the work instruction, assembly drawings, and the assembly configuration. The assembly lines typically consist of

- printed circuit board assembly lines
- sub and final assembly lines
- packaging lines

Then, all *parts and components* listed in the bill of materials are delivered to the assembly lines and assembled according to the assembly drawings and work instruction. The parts and components are grouped into

- packaging materials
- accessories
- functional parts (mechanical, electronic and electrical)

In the 'out-of-box' inspection, the product is validated as a complete customer set, then the set is unpacked and disassembled piece by piece and checked against the accompanying information, the assembly configuration, and the parts/components. In trial-run, the validation begins with inserting minute electronic components into printed circuit boards and goes on to packing the fully complete and functional product.

Product validation focuses on the items within the three product characteristics, i.e. information, process and parts/components, and the identification of non-conformances should be directed on these items. The new classification introduced is thus based on these three characteristics.

4.2.2.2 New Product Non-conformance Classification

The research has identified product non-conformance in pre-production as having two distinctive aspects:

1. *Non-conforming items are the results of mistakes.* These mistakes such as omitted information, wrong material and defective material, as shown in Figure 4-3, have been identified in the product's characteristics. For example, they are mistakes in drawings, in sub-assemblies or mechanical parts.

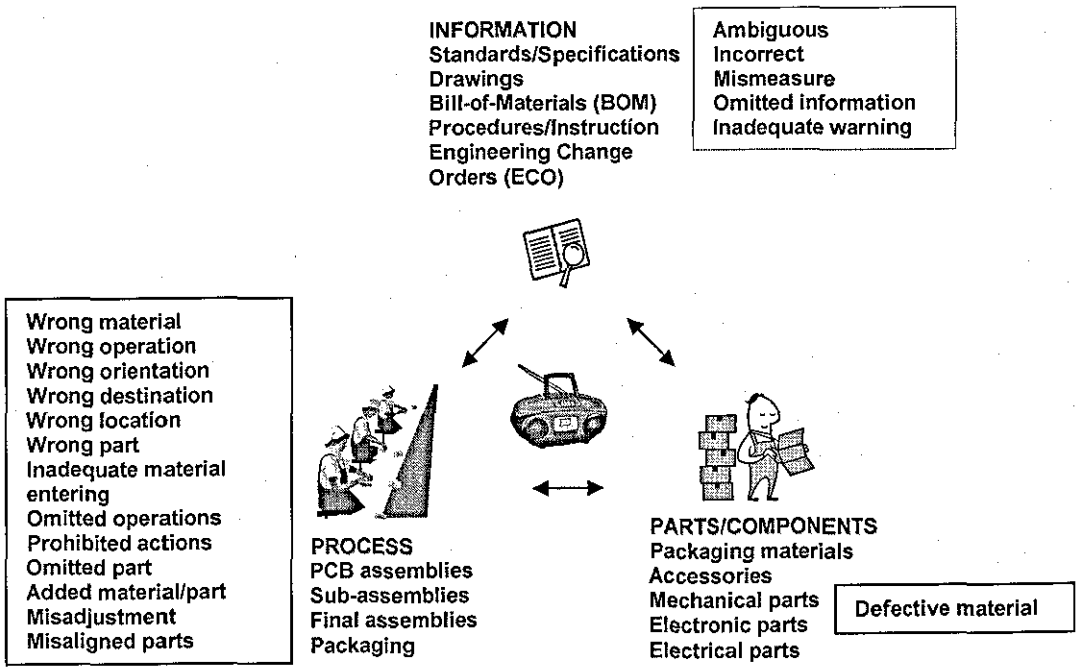


Figure 4-3 Relationship between product characteristic and type of mistakes

2. *Non-conformances manifested in the three product characteristics.* Mistakes which result in non-conformances can be rapidly identified since they are manifested within the three product characteristics. Figure 4-3 above shows that mistakes may occur in any items in the product characteristics, for example omitted information in drawings leads to Information non-conformance, wrong material in sub-assemblies corresponds to Process non-conformance, and defective material in a mechanical part will represent Parts/Components non-conformances.

Thus, based on these two aspects, a new generic classification of non-conformances which relates to mistakes and product characteristics is introduced known as the *Product-based Non-conformances Classification* or *PNC*. The classification consists of three types of non-conformances corresponding to the product's characteristics and mistakes,

1. Information Non-conformances
2. Process Non-conformances
3. Parts/Components Non-conformances

Other than introducing a new non-conformance classification into pre-production, the PNC is seen as an extension of the Outcome-based Mistakes Classification or OMC (Hinckley, 2001). The novelty of PNC is characterised by:

- classification of non-conformances based on *mistakes manifested in the characteristics of product under validation,* during out-of-box and trial-run inspection in the pre-production of consumer electronic product. However, the OMC classifies mistakes based on *the consequences of mistakes* detected in product and production processes in the general manufacturing industry, and grouped into defective material, information mistakes, misses, selection mistakes, and omission/commission mistakes. Table 4-1 shows the comparison between the PNC and the OMC in relation to type of mistakes.
- *a high level non-conformance classification,* which is important to provide a holistic understanding the occurrence of mistakes in individual components/items of the product characteristic, as shown in Figure 4.3 above. This is in contrast to the OMC which grouped mistakes further into *simpler generic classes* based on the consequence of mistakes without describing the exact occurrence of each class of mistakes. For example, misses is not defined whether it is related to missing information, missing parts/components or missing task during assembly.

The similarity between PNC and OMC, however, is the *type of mistakes* identified on products either under validation or running in production lines. As the name implies, in pre-production the validation considers identifying and preventing non-conformances related to production, therefore these mistakes should be addressed.

Table 4-1 PNC, OMC and type of mistakes

Product-based Non-conformance Classification		Type of mistakes	*Outcome-based Mistakes Classification*
INFORMATION	Technical specifications Work instructions BOM Drawings ECO	Ambiguous information Incorrect information Misread, Mismeasure, Misinterpret, Omitted information, Inadequate warning	*INFORMATION MISTAKES*
PROCESS	PCB assemblies Sub-assemblies Final assemblies Packaging	Omitted operations Wrong part Wrong orientation Wrong operation Wrong location Wrong destination	*MISSES* *OMISSION OR COMMISSION MISTAKES* *SELECTION MISTAKES*
PARTS/ COMPONENTS	Packaging materials Accessories Mechanical parts Electronic parts Electrical parts	Defective materials	*DEFECTIVE MATERIALS*

Table 4-2 illustrated the enhancements to the Outcome–based Mistakes Classification or OMC (Hinckley, 2002), shown in italics. The OMC grouped mistakes into five classes which are *Information Mistakes (IM), Misses (MS), Omission/Commission Mistakes (OC), Selection Mistakes (SM)* and *Defective Material (DM)*. This classification is used in identifying mistakes in production in common manufacturing industry. From the industrial investigation in the pre-production of a consumer electronic manufacturing company, as described in Chapter 3, it has been shown that:

- In validation, these mistakes are also manifested during the out-of-box and trial-run inspection.
- These mistakes led to non-conformances associated with the three characteristics of product under validation (in bold), which are Information (I), Process (P) and Parts/Components (PC).

It has been shown that mistakes grouped under *IM* also correspond to mistakes that lead to Information non-conformances identified in pre-production. Mistakes in *MS, OC*, and *SM* correspond to causes of non-conformances in Process; and defective material (*DM*) leads to Parts/Components non-conformances. Hence, extending the OMC, another classification is suggested, known as the *Product-based Non-conformance Classification* or *PNC*. This represents a high level generic non-conformance

classification applicable in the context of the pre-production of consumer electronic products.

This table also illustrates the relationship matrix between one mistake and another. For example, wrong operation (Process Non-conformance) is strongly associated with defective material (Parts/Components Non-conformance), incorrect information (Information Non-conformance), and omitted operation. This ensures that potential non-conformances are not ignored or overlooked. This table depicts holistically how mistakes, product characteristics and non-conformances are interconnected. Reflecting the case of the safety label in Chapter 3, the regulation (Information) requires the product to have the safety label, followed by the supply of the correct label (Parts/Components), then the task (Process) of placing the label appropriately is determined; hence, they are interrelated. If the label is not attached to the product, other items are checked for whether there is a need for the label in the regulation, or the label has been mistakenly missed during assembly, or a wrong label has been supplied. Non-conformances can manifest themselves in any of the three conditions. Therefore it is important to identify other potential non-conformances within the three product characteristics.

Table 4-2 Illustration of PNC (in bold), OMC (in italics), type of mistakes and the connection among mistakes.

⊙: Strong Connection O: Connection Blank: Weak/No Connection			**PC**	**I**					**P**												
			dm	*im*					*ms*			*oc*				*sm*					
				Ambiguous	Incorrect	*Mismeasure, interpret*	Omitted Information	Inadequate Warning	Misalign	Misadjust	Mistimed or Rushed	Added Parts	Prohibited Act	Omitted Operation	Omitted Parts	Wrong Material	Wrong Destination	Wrong Location	Wrong Operation	Wrong Parts	Wrong Orientation
PC	*dm*								O	⊙	⊙		O	⊙	⊙				⊙	⊙	⊙
I	*im*	Ambiguous				⊙			⊙	⊙				O				O	⊙	⊙	O
		Incorrect				⊙				⊙	⊙		⊙			O	⊙		⊙		
		Mismeasure	O	⊙	O				⊙	⊙	⊙					⊙		O			O
		Omitted Information							O	O			⊙	O	O	⊙		O	O	O	
		Inadequate Warning							⊙	⊙	⊙										
P	*ms*	Misalign	O	⊙		⊙	O	⊙		⊙	⊙			O	O			⊙			⊙
		Misadjust	⊙	⊙	⊙	⊙	O	⊙	⊙		⊙		O					O			O
		Mistimed or Rushed	⊙		⊙	⊙		⊙	⊙	⊙			O	⊙	⊙		O	O	O	O	O
	oc	Added Parts											⊙		O					O	
		Commit Prohibited	O		⊙		⊙			O	O	⊙				O					
		Omitted Operation	⊙	O			O		O		⊙				⊙	⊙			⊙		
		Omitted Parts	⊙				O		O		⊙	O		⊙				O	O	O	
	sm	Wrong Material			O	⊙	⊙						O	⊙					⊙	⊙	
		Wrong Destination			⊙						O							⊙		⊙	
		Wrong Location		O		O	O		⊙	O	O				O		⊙		O	O	⊙
		Wrong Operation	⊙	⊙	⊙		O				O			⊙	O	⊙		O		⊙	⊙
		Wrong Parts	⊙	⊙			O				O	O			O	O	O	O	O		O
		Wrong Orientation	⊙	O		O	O		⊙	O	O							⊙	⊙	O	

Source: Adapted from Hinckley (2001).

Note:
PNC: PC=Parts/components; I=Information; P=Process
OMC: *dm*=Defective Material; *im*=Information mistakes; *ms*=misses; *oc*=omission/commission; *sm*=selection mistakes

Hence, identifying non-conformances as the result of mistakes on the individual items of the product's characteristics is much simpler. Once non-conformances are identified, it is easier to deal with the consequences and solutions, and to learn from mistakes (Gillingham et al., 1997). This section has described a new approach to identifying and classifying non-conformances in pre-production which is called the Product-based Non-conformance Classification or PNC. Non-conformances can be identified and classified by taking into account,

1. mistakes as the cause of non-conformances,
2. characteristic of the products under validation.

The PNC is amalgamated with a control method formulated and explained in the following section.

4.2.3 Non-conformance Consequences and Solutions Methodology

In order to control product non-conformance, non-conforming items should be appropriately analysed to determine the consequence/solution. The analyses are tabulated in a matrix consisting of two components: *the consequences and the solution of non-conformances*. This method is called the Non-conformance Consequence and Solution or NoCoS methodology. Unlike the two methods described in Section 4.2.3 which are the FMEA and the Simple Severity Ranking, the NoCoS methodology analyses non-conformances with the following approach:

- indicates non-conformances in a simple two-dimensional matrix,
- analyses non-conformances based on product safety, producibility and customer perception,
- defines non-conformances on the consequence level and solution condition.

4.2.3.1 Analysing Product Non-conformance

This method is adapted and customised from the method of analysing product reliability problems in the Product Development Process called the Reliability and Quality Matrix or RQM (Yuan, 2002), as described in Chapter 2. However, the NoCoS is used to analyse product non-conformance in pre-production. While the former method defines reliability problems based on the severity and status of the reliability problems, NoCoS defines product non-conformance based on the consequence level and solution status of the non-conformances. The description on the status of the reliability problems (Gravity Factors) and the severity (Evolution Factors) used in the RQM shown in Table 4-3 are found to be relevant (except Evolution Factor 4); and have been customised as the Consequences Levels and Solution Status in the NoCoS matrix, as shown in Table 4-4.

Table 4-3 RQM description

Gravity factors	*S-problem: non-conformity with safety standard/other safety requirement.* *A-problem: results in not producible or not saleable product* *B-problem: results in product that can be produced but with big problems or will not be accepted by critical customer* *C-problem: results in product that can be sold or produced with minor difficulties* *D-problem: accepted by management – no activities will be started to reduce or eliminate this problem*
Evolution factors	*4: cause not known* *3: solution not known* *2: evaluation not yet positive* *1: solution not yet introduced* *0: solution introduced*

Source: Yuan (2002)

Table 4-4 NoCoS description

Consequence Level	**C1 :** non-conformance with **safety** standard and requirement. **C2 :** non-conformance that results in a **not producible** product. **C3:** non-conformance that results in product that can be produced but with big problems or will not be accepted by **critical** customer. **C4 :** non-conformance that results in product that can be sold or produced with **minor** difficulties. **C5 :** non-conformance **accepted** by management – no activities will be started to reduce or eliminate this problem (this is considered as a non-problem).
Solution Status	**S1** : solution not known **S2** : solution not yet positive **S3** : solution known but not yet introduced **S4** : solution known and introduced

The NoCoS methodology consists of two components:

1. To determine the consequences, five levels of non-conformance are identified and coded as C1, C2, C3, C4, and C5. C1, being the most severe, is treated as the highest priority.
2. To determine the solution, four types of non-conformance status are identified and coded as S1, S2, S3 and S4. S1 is the condition where the solution of a non-conforming item is not yet known, while the others have known solutions.

4.2.3.2 Prioritising Product non-conformance

The NoCoS matrix consists of five columns corresponding to the levels of non-conformance consequences - C1, C2, C3, C4 and C5, and five rows of the non-conformance solution status - S1, S2, S3, S3 and S4, as shown in Table 4-5. Non-conformances are identified and logged into the appropriate cells, which show the quantity of accumulated non-conformances.

Table 4-5 NoCoS matrix

		Non-conformance Consequence Level				
		C1	C2	C3	C4	C5
Solution Status	S1					
	S2					
	S3					
	S4	x				

The NoCoS matrix is read as follows, any values in or near cells C1 and S1 indicate the severity of a non-conformance, while any values in or near cells C5 and S4 indicate the less significant and negligible type of non-conformances. These conditions are determined by

- the consequence of a non-conforming item for safety, production activities and customer perception (see Consequence Level description). For example, in Case 1 in Chapter 3, safety non-conformance is the most serious (C1) and represents the highest priority, which requires the company to take immediate action.
- the existence of the known solution to solving non-conformances (see Solution Status description). Whilst unknown solution warrants immediate investigation, the known solution can be implemented immediately.

Non-conformances are identified and logged into the NoCoS matrix according to consequences and solution status. For example, as demonstrated in Case 3 in Chapter 3 on the missing safety label, this is a severe non-conforming item because the product fails to conform to product safety regulation and requirement, which may jeopardise the customer as well as the company's business. If the non-conformance has a known solution, action can be implemented immediately.

Therefore, Case 3 is logged into cell C1-S4 (shown as *x*). Additionally, the NoCoS methodology also indicates that certain non-conformances are a compromise and negligible, whilst some of the solutions are still under scrutiny and evolve gradually.

The decisions to determine the consequence level and solution status of non-conformances are based on archives data and experience. Hence it is imperative to have a database or repository of previous data or information related to non-conformances, the consequences and the solutions, whilst valuable knowledge from experienced staff is shared and reused.

This section described the method to control product non-conformance in pre-production known as the NoCoS methodology. Non-conformances are analysed and prioritised based on the matrix of two components - the severity of the consequence of non-conformances, and the solution to the non-conformances. The emphasis of the controls is on product safety, producibility and customer perception of a product. Non-conformances can thus be identified and controlled holistically during the product validation process in pre-production.

4.3 SUMMARY

The research focuses on product non-conformance as the results of mistakes, and the three characteristics of product in pre-production - information, process and parts/components. This research contributes to:

1. the classification of non-conformances is based on the product characteristics and mistakes, named Product-based Non-conformances Classification, or PNC.
2. the control of non-conformances is based on the consequences and the solution of the non-conformances, named Non-conformance Consequence/Solution or NoCoS methodology.

The implementation of these methodologies is in the form of a product validation workbook described in the following chapter. The workbook presents a step-by-step

guideline to the deployment of the PNC and NoCoS methodology during the product validation process. The concept introduced in this chapter contributes to identify and control non-conformances, improve the product validation process in pre-production, and facilitate decision making in the product development process.

CHAPTER 5

FORMULATING IMPROVED PRODUCT VALIDATION PROCESS

5.1 INTRODUCTION

This chapter explains the formulation of improved product validation in a workbook through which the research ideas are deployed. The workbook to act as a guide to the validation process has been formulated based on the new approaches of the Product-based Non-conformance Classification (PNC) and the Non-conformance Consequence and Solution (NoCoS) methodology, as described in Chapter 4. An example of the validation workbook is given in Appendix B.

This chapter consist of three main sections. Section 5.2 describes the workbook structure. Section 5.3 explains the main part of the workbook, which is the step-by-step validation process. Section 5.4 describes the aspect of the improved validation process.

This chapter, together with Chapter 4, completes the discussion of the research ideas in this thesis. The evaluation of the research ideas is presented in Chapter 6.

5.2 WORKBOOK STRUCTURE

The validation process workbook is a guide to perform product validation in pre-production. Some parts of the validation process described in the workbook follow a conventional practice (Anderson, 1975); however, the proposed new approaches of the PNC and the NoCoS have been introduced into the process. Therefore, the workbook describes the operation of the validation process with the aim of deploying the new approaches introduced in Chapter 4.

The workbook describes the step-by-step procedure for validating products, and is divided into three sections: Section 1 – Overview, Section 2 – Definitions, and Section 3 – Validation Process, each of which is discussed in the following sections, respectively.

5.2.1 Section 1 - Overview

Section 1 of the workbook provides an overview so that readers have a comprehensive understanding about the workbook and the product validation process. The purpose of the workbook is to provide a simple and easy-to-use guide in validating products. The introduction briefs on product reviews in PDP, and the issue of product quality and product validation in pre-production. The scope of the workbook is the identification and control of non-conformances due to mistakes.

Inspection and testing are the means of validating products; however, only inspection is referred to in the workbook. In this context, the inspection validates the product and the trial-run for the integrity, conformances and non-conformances, but not to perform measurement (Ishikawa, 1990) on the performance and reliability of the product under validation.

In this section, the product validation process is illustrated based on the IDEF0 activity modelling method (Bal, 1998; Cheung and Bal, 1998; Dorador and Young, 2000) as depicted in Figure 5-1. The model is adopted as it represents the validation process, and the associated elements and their relationship, in an easy to understand model which non-experts can view and understand (Dorador and Young, 2000). The validation process and the elements are composed of Input, Output, Controls, Mechanism and Process. The *input* represents the product to be validated, either new or improved product. The *output* is the product which completes validation in two conditions: (1) the product is in conformance and qualifies for production, and (2) the product is non-conforming and requires further action. The *control* represents the three consideration and references - information, process and parts/components, employed in the validation. The *mechanism* for checking the product's conformities and non-conformities is inspection. The *process* is the conduct of the validation which relates to all four

elements described earlier, involving five steps, as illustrated by the validation process sequence diagram. These elements are discussed further in Section 5.3.

This section also briefly describes the five steps of the validation process and their objectives. The steps are presented by a flow diagram showing the sequence of the steps and the activities corresponding to each step.

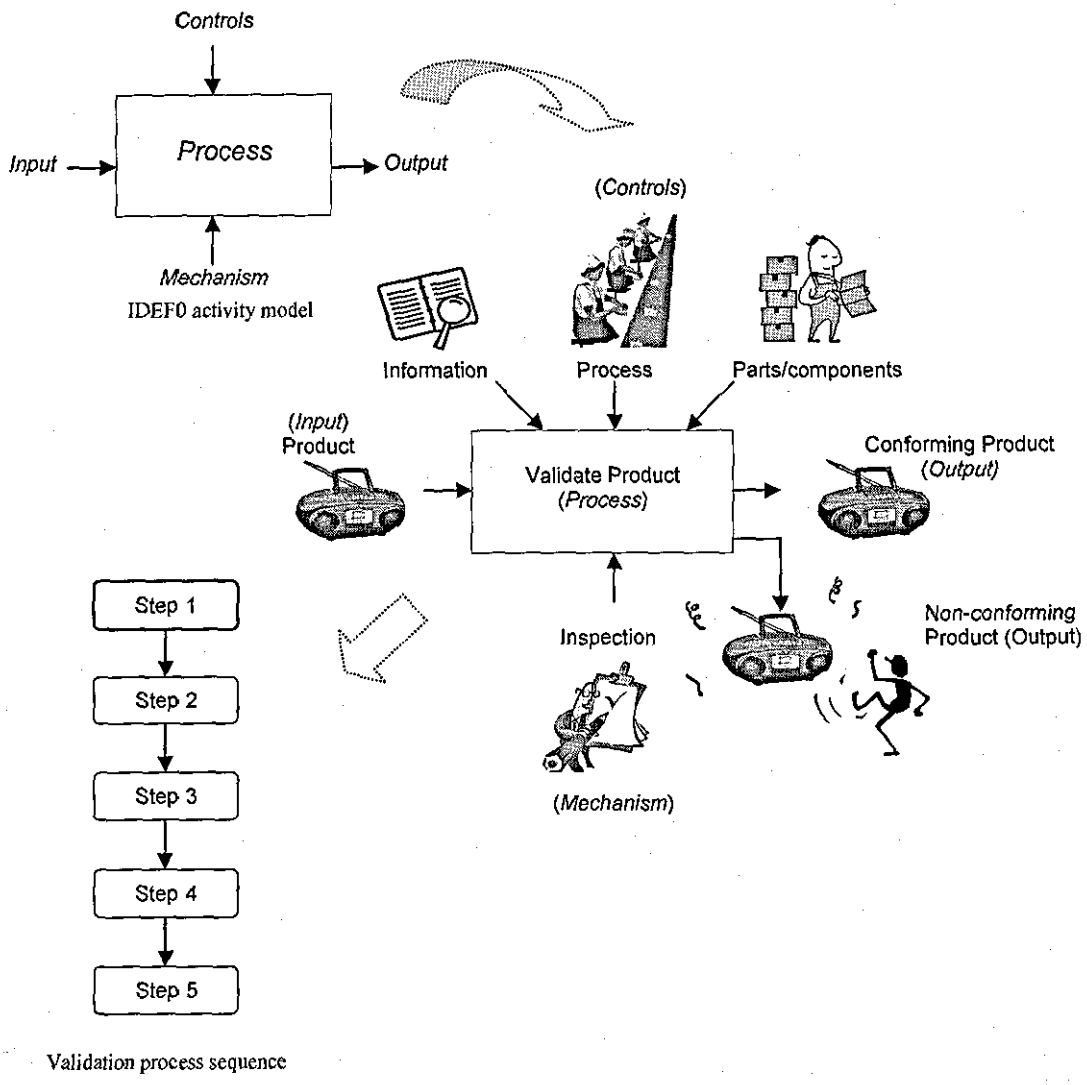


Figure 5-1 Product validation process

5.2.2 Section 2 - Definitions

Section 2 explains the common terms used throughout the workbook. The workbook uses the terms which should be easy to understand by non-technical readers.

5.2.3 Section 3 – Validation Process

Section 3 explains the validation process which covers the major part of the workbook. The validation process involves five steps: Step 1 – Initiation, Step 2 – Detection, Step 3 – Analysis, Step 4 – Rectification, and Step 5 – Prevention. The new approaches, the PNC and NoCoS, are deployed in Steps 2 and 3, respectively. The significance and the relationship of each step and the new approaches are summarised in Table 5-1. The table describes the general rules and the fives steps in relation to the PNC/NoCoS. Each step is explained against,

- *purpose* - briefs on the objectives of the procedures,
- *procedure* - lists the main tasks to achieve the purpose, and
- *activities* - explains the modus operandi of the procedures.

Table 5-1 Validation process steps and their significance to new approaches

Validation Process	Significance
General Rules	Facilitates PNC and NoCoS in ensuring non-conformances are identified and controlled extensively prior to production.
Step 1 - Initiation	Provides understanding about the product's characteristics which correlated with the PNC.
Step 2 - Detection	Provides input to PNC from which non-conformances identified during inspection are manifested in product as a result of any mistakes.
Step 3 - Analysis	Defines non-conformances according to consequences and solutions, and as input to NoCoS matrix for further action.
Step 4 - Rectification	Implements decisions corresponding to NoCoS methodology.
Step 5 - Verification	Confirms that initiation, detection, analysis and rectification were conducted and deployed rigorously, which includes exercising PNC and NoCoS methodology.

The validation process has been significantly influenced by the case studies of product non-conformance, as presented in Chapter 3. These case studies are referred to in the following section to aid the explanation of the workbook.

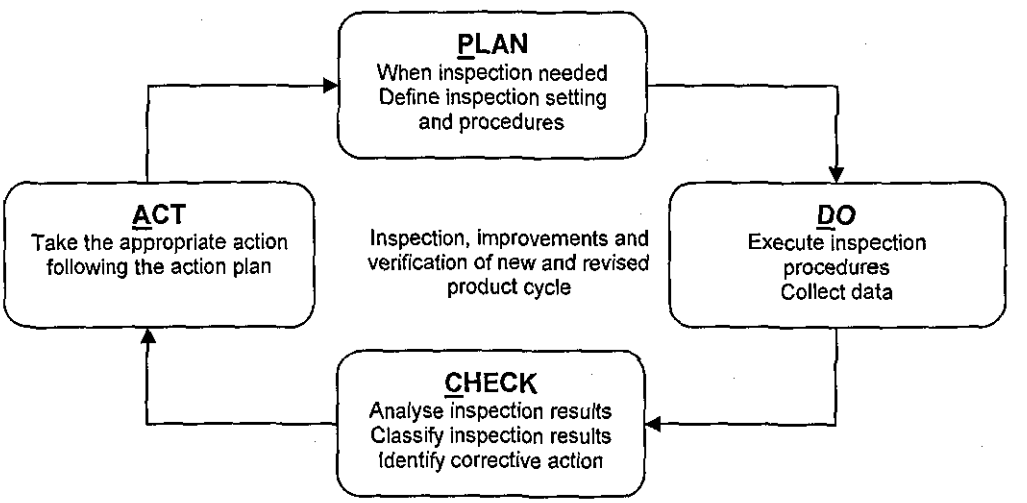
5.3 STEP-BY-STEP VALIDATION PROCESS

This section explains the validation process in the workbook in terms of

- theoretical basis of the validation process,
- general rules of the validation process,
- five steps of the validation process,

5.3.1 Theoretical Basis of Validation Process

Validation is a method of product assessment, and also a continuous improvement effort, as well as a learning activity (Ebenau and Strauss, 1990). Validation delivers continuous improvement to the product and the validation process itself, whilst it provides a learning opportunity to the validation team, the product development programme, and the organisation (Cole, 2001). Deming's PDCA or the Plan-Do-Check-Act cycle (Deming, 1986; de Theije et al., 1998), as depicted in Figure 5-2, is thus appropriate to represent the operation of the validation process.

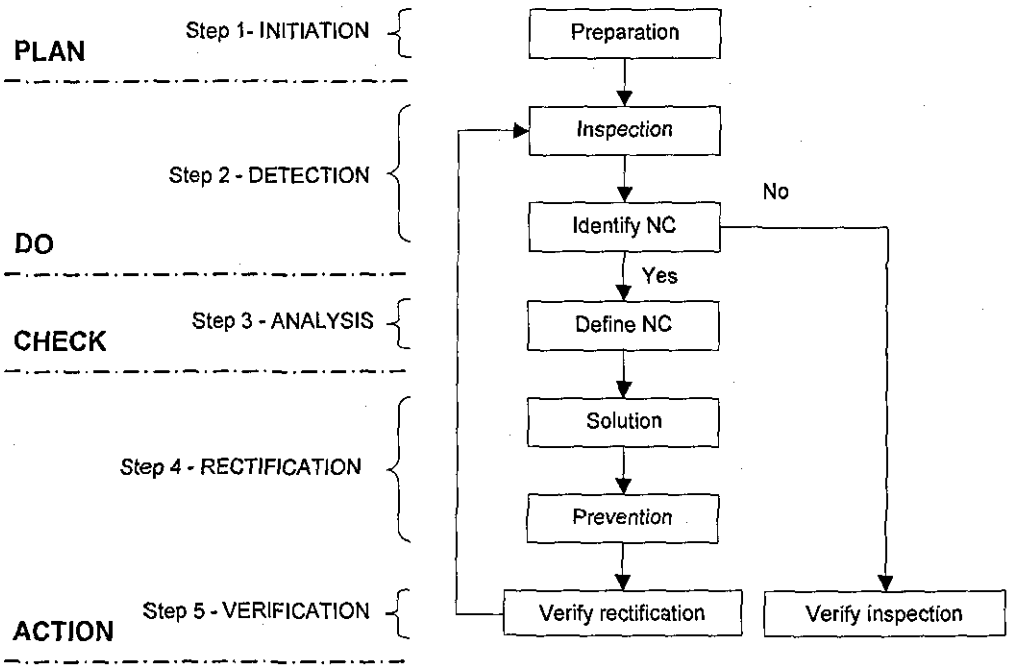


Source: Adapted from de Theije et al. (1998)

Figure 5-2 PDCA cycle

The PDCA works in synergy with the validation process, as depicted in Figure 5-3. Step 1 – Initiation, *preparation and planning* is initiated, such as the paper-work or documentation; validation team involve in the inspection; and the product to validate. Step 2 – Detection, after completed the planning, the validation team *perform*

inspection to identify non-conformances in the product and the production process. Product without non-conformances is verified and completes the validation process, in Step 5 – Verification. Step 3 – Analysis, the product with non-conformances undergoes analysis to define the items which divert from specification and quality. In this step, non-conformances are classified and prioritised according to the consequences and the solutions. In Step 4 – Rectification, the solution and prevention are to be deployed, then Step 5 – Verification, to verified that they have been implemented satisfactorily. These steps are *reiterated* on the same product until it demonstrates that non-conformances have been removed and it is fit for full production.



Note: NC = non-conformances

Figure 5-3 Workbook structure based on PDCA-Validation process

5.3.2 General Rules

The validation process is deployed with a set of general rules for the validation team to follow in strict adherence. Failure to do so jeopardises the validity of the product under validation. Most importantly, the general rules facilitate the PNC and NoCoS methodology in ensuring non-conformances are identified and controlled extensively. There are three general rules which guide the validation process:

1. 100 % Inspection - ensures that the inspection covers all aspects of the product and trial-run.
2. Rapid Analysis - non-conformances are investigated, defined, and rectified promptly.
3. Extensive Prevention - the strategy to avoid the recurrence of non-conformances implies both temporary and permanent solutions.

Since non-conformances can only be controlled with 100% inspection (Hinckley, 1997), the first rule dictates the validation team must carry out a *100% inspection* on the product and the trial-run. Three aspects of the product are to be inspected: the information, process, and parts/components. Full inspection is possible, although at first glance, this rule may be difficult to achieve due to the constraint of the short duration of validation. The inspection is to identify tangible and potential non-conformances on specific final consideration, and the PNC introduced in the workbook (Step 2 - Detection) provides a holistic approach to identify the non-conformances. Consequently, the inspection is much faster, and furthermore, there are not many products to validate.

The second rule is the *rapid analysis of the non-conformances*. Archive records and feedback from the members of the validation team are crucial in investigating the causes, in defining and prioritising non-conformances, and in deciding the rectification strategy. This is achieved through Step 3 Analysis which uses the NoCoS concept described in Chapter 4.

The inspection and analysis rules adopt the PNC and NoCoS methodology, depicted by a validation scenario as shown in Figure 5-4. Product information, process and parts/components are inspected for the manifestation and potential mistakes, either specific or multiple mistakes, and defined based on the PNC. Non-conformances are analysed and assessed using the NoCoS method to establish the level of seriousness, followed by identifying the solutions status, either known or unknown. Further actions which are rectification and prevention of non-conformances are to proceed from these two activities.

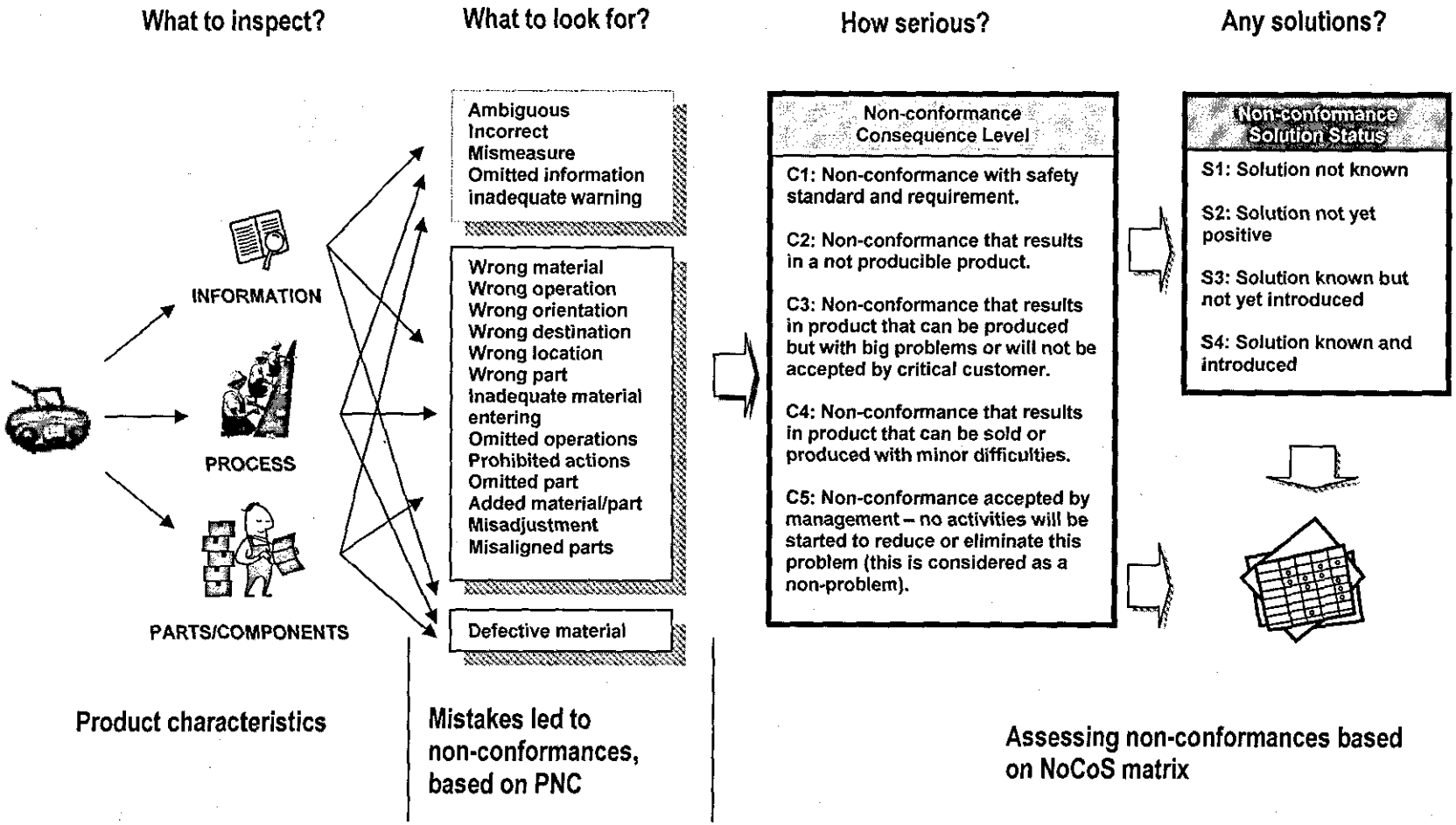


Figure 5-4 PNC and NoCoS application scenario

The validation process is completed with the verification that the validation process and the solution to the non-conformances are implemented appropriately. In the industry, the solution is divided into two types: temporary and permanent. The temporary solution is deployed on an initial batch of production, yet does not guarantee that non-conformances will not recur. For example, the case of the protective pads described in Chapter 3, Section 3.3.1, where the operator forgets to fix the pad during production. The permanent solution is implemented on the subsequent improvement to the product. Therefore, an *extensive prevention plan*, which is the third rule, is to be formulated to avoid non-conformances from recurring. Techniques such as mistake-proofing (Shingo, 1986; Hinkley, 2001), described in Chapter 2 Section 2.4.5, are appropriate in pre-production.

The next section describes each step of the validation process, as presented in Section 3 of the validation workbook.

5.3.3 Step 1 – INITIATION

The initiation step provides the understanding of the characteristics of the product under validation which correlated with the PNC. These characteristics represent all the considerations and the tangible items to be validated.

The *purpose* of the initiation is to prepare the validation team to inspect the product and the trial-run. The initiation *procedure* begins with a meeting of the validation team, which represents the Engineering (as mediator in pre-production), Design, and Production teams. In the meeting, necessary preparations, such as the documentation, the assembly lines for trial-run, and the product under validation, are finalised. The initiation *activities*, depicted in bold in Figure 5-5, are centred in a meeting where the validation team prepares, discusses and familiarises itself with the product's characteristics (information, process and parts/components), as listed below, and the trial-run.

INFORMATION	PROCESS	PARTS/COMPONENTS
Specifications Instruction Bill of Materials (BOM) Drawings Checklist Engineering Change Orders (ECO)	PCB assemblies Sub-assemblies Final assemblies Packaging	Packaging Accessories Mechanical parts Electronic parts Electrical parts

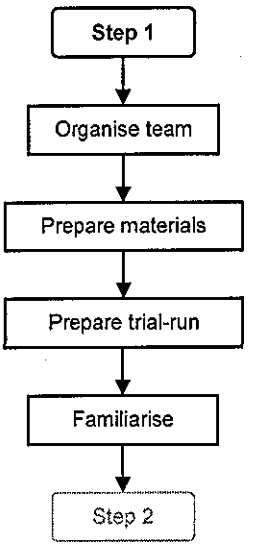


Figure 5-5 Step 1 – INITIATION activities flow diagram

5.3.3.1 Preparing Information

The preparation for the *information* aspect of the product under validation focuses on the key documentation, which are technical specifications, work instructions, bill-of-materials, drawings, checklist, and engineering change orders.

The Design team has the task of ensuring that all relevant information is delivered, and that the particulars are correct, consistent, and reliable. For example, the team has to ensure the correct safety specification and requirements, such as safety messages and certification labels for the appropriate product. The Engineering team considers the product's conformance to specification and quality requirements, as stated in the checklist, assembly drawings and technical specification. For example, the Engineering team ensures that information about the product's safety messages and certification labels is accurate, as described in those documents. The Production team focuses on

accurate, reliable and complete information to assemble the product with ease, according to the specification. For example, the team focuses on the correct and complete set of work instructions, assembly drawings and the bill-of-materials to assemble all the safety parts/components (safety/certification labels, power cord, harnesses, etc.), using the correct parts and quantity. This variation in the preparation of information considerations among the validation team is depicted in Figure 5-6.

Team	*Considerations*
Design	Information about safety messages and certification labels for product under validation.
Engineering	Safety messages and certification labels conform to documentation.
Production	Information about how safety messages and certification labels are to be deployed.

Figure 5-6 Variation in validation team's information considerations

The variation must be understood during the preparation meeting. Each member of the validation team checks the drawings, instructions, checklist, and other related information related to the product, process and parts/components has been satisfactorily established, documented, and presented appropriately.

5.3.3.2 Preparing Process

The preparation for the *process* aspect of the product under validation focuses on the trial-run assembly lines. Typical assembly lines consist of PCB assemblies, Sub-assemblies, Final assemblies, and Packaging.

The assembly lines are prepared by the Production team, based on the product's assembly configuration, as stated in the assembly drawings and work instructions. At this stage, it is essential for the Production team to address the meeting about the assembly line's constraints and uncertainties. If the product's assemblies are complicated, require substantial tasks, and are vulnerable to mistakes, the process may contribute to non-conformances. For example, in the case of the missing safety/certification labels (Case 1 in Chapter 3), the label will not be missed if clearly displayed in the work instructions and design drawings. However, imprinting a box

shape on the product's back panel, as depicted in Figure 5-7, improves visibility and ensures the label will not be missed out during assembly, and even during prototyping. In addition, the imprint does not affect the product's aesthetics and quality.

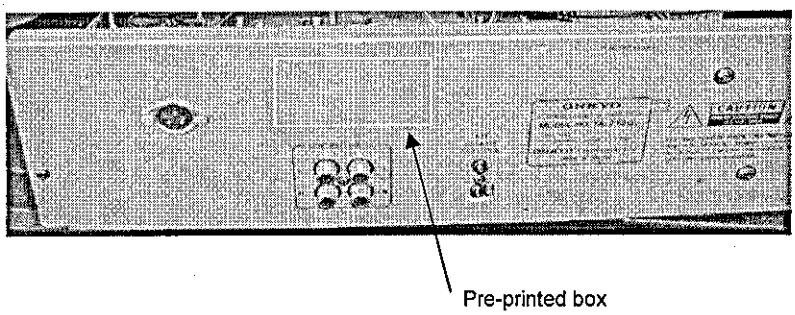


Figure 5-7 Pre-printed box avoids mistakes (missing label).

Hence, this meeting highlights and streamlines both design and production considerations, prevents non-conformances, and enhances efficiency of the assembly line.

5.3.3.3 Preparing Parts/Components

The preparation for the *parts/components* aspect of the product under validation focuses on the correctness of the parts and components assembled as a finished product and those supplied for assembly in the trial-run. Typical parts/components of consumer electronic products are composed of packaging materials, accessories, mechanical parts, electronic parts, and electrical parts.

Correct parts/components produce quality finished products, and can be assembled according to the work instructions. To ensure the correct parts/components, the validation team studies and familiarises themselves with the product as an 'out-of-box' set, the individual parts/components, and the assembly configuration.

Although there are thousands of parts/components in a single product, recognising them is not difficult, as most of them are similar. The parts/components are to be compared with the Information aspects (the detailed drawings, assembly drawings, work instructions and bill-of-materials) and Process aspects (assembly configuration). Any

non-conformances in the parts/components are critical, since they relate to the procurement and fabrication of each of them.

In summary, the information process, and parts/components characterise the product under validation. These interrelated characteristics are pertinent in the identification of non-conformances in the validation process. The conduct of Step 1 – Initiation requires the validation team to understand and be familiar with these characteristics and their interrelationship. The team should be prepared to inspect the integrity and non-conformances of the product. Hence, the initiation step is a meeting session to finalise:

- all the inspection considerations are clearly addressed among the validation team,
- the inspection checklist and other relevant documentation for the inspection are ready,
- the preparation for the product, trial-run, and the parts/components is complete.

Therefore, the initiation step described in the workbook is the first and essential step in the identification of product non-conformance in terms of PNC. After this step, the validation team proceed to the next Step 2 – Detection.

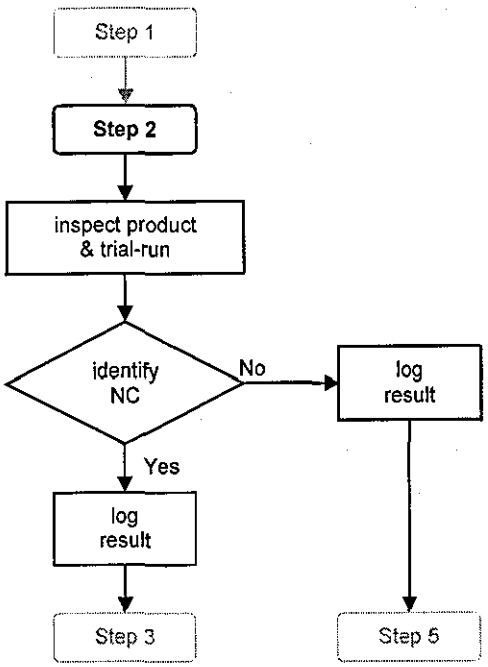
5.3.4 Step 2 – DETECTION

The detection step identifies non-conforming items which are to be classified according to the PNC. The non-conformances are manifested in the product and trial-run as a result of various mistakes. These items are scrutinised further, and subsequently three types of non-conformances have been identified as Information Non-conformances, Process Non-conformances and Parts/Components Non-conformances.

The *purpose* of detection is to identify non-conformances in the product under validation, by means of inspection. Inspection is referred to as gathering information on the product, and comparing the product with what was intended or specified. The inspection performs (Winchell, 1996):

- detecting of good artefact from defective artefact,
- diagnosing of problems by providing information about the problems, and
- data gathering for future reference, traceability, sharing, and dissemination of information.

This definition of inspection fits appropriately as the mechanism for validating product in pre-production. The *procedures* are centred on inspecting the product and the trial-run based on the two-phase inspection sequence. The detection *activity* focuses on identifying non-conformances and logging the inspection results, as depicted in bold in Figure 5-8.



Note: NC:=non-conformances

Figure 5-8 Step 2 – DETECTION activities flow diagram

5.3.4.1 Inspecting product and trial-run

The inspection is conducted in two phases. Phase 1 is the *out-of-box inspection,* where the validation team checks the product against the product's characteristics, and focuses on accessories items (for example remote control, speakers, instructions), cosmetics or appearance, functions and features, assembly configuration, for example opening/removing the cover panels, and individual parts and components. Phase 2 is the *trial-run inspection,* where the validation team checks the assembly capability. The inspection focuses on parts/components used to assemble the product, assembly aids

such as the assembly drawings and work instructions, and assembly operation - PCB assemblies, sub-assemblies, final assemblies, and the packaging.

The two phases of inspection are depicted in Figure 5-9, and each item in the product under validation is listed in detail in Annexe 1 of the workbook.

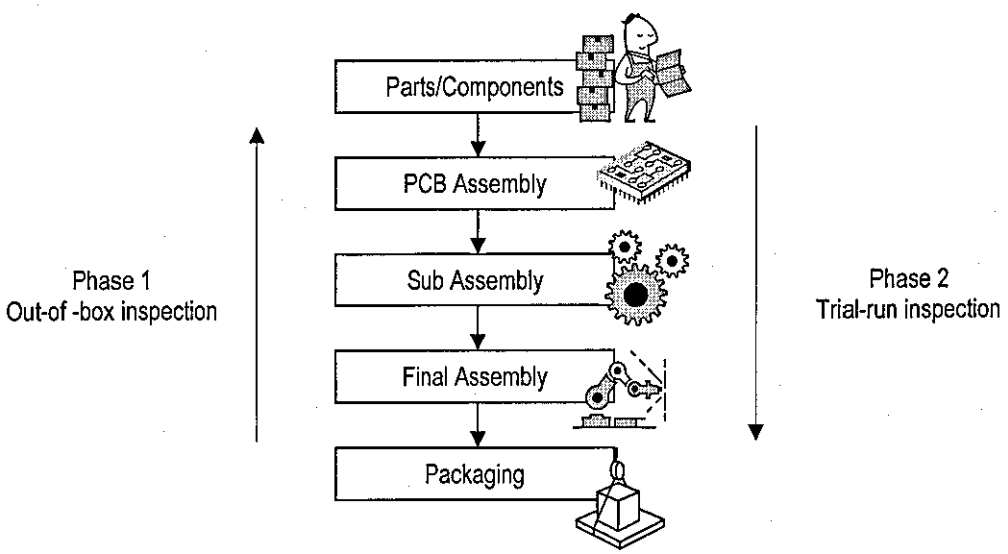


Figure 5-9 Two-phase inspection sequence

5.3.4.2 Identifying non-conformances

The essential inspection tool is the checklist. This list should be formulated to represent the items to be validated against the tangible and potential mistakes related to the items, described objectively and accurately. The checklist is to be depicted as shown below, for the validation team to identify/describe the mistakes which result in non-conformances.

Inspection items	**Result**	
1. Safety/certification labels and marking on back panel	attached	omitted
2. Safety/certification labels and markings shown 'CE'	correct	incorrect
3. Safety/certification labels and markings position	correct	incorrect
4. Safety/certification labels and marking print	adequate	inadequate

As an example, the tangible and potential mistakes on product safety, such as the label on the back panel, are incorrect information, omitted information, inadequate warning, and wrong location, as shown in Figure 5-10. Examples of non-conformances as a consequence of mistakes are shown in Table 5-2. The workbook provides a list of various types of mistakes and their correlation among the three classes of non-conformances (see Annexe 2), which can be used as a guide to formulate a checklist, as in the example above.

Table 5-2 Classes, and location of non-conformances, and potential mistakes.

Class of non-conformance	Locality of non-conformances	Type of mistakes	Description of mistakes
INFORMATION	Technical Specifications Work instructions Bill-of-Materials Drawings Checklist Engineering-Change-Order	Ambiguous Information	Information can be interpreted many ways, some interpretations may be incorrect.
		Incorrect Information	Information provided is incorrect.
		Misread, Mis-Measure, Misinterpret	Gauge-reading errors, errors in measuring, or errors in understanding correct information.
PROCESS	PCB assemblies Sub-assemblies Final assemblies Packaging	Omitted Operations	Failure to perform the required operation.
		Wrong Part	Part selected, but wrong part.
		Wrong Orientation	Part inserted in correct location, but the part has wrong orientation.
		Wrong Operation	Operation executed, but wrong operation.
		Wrong Location	Part insertion or process execution in incorrect location that is not the result of incorrectly orienting parts.
		Wrong Destination	After completing operation, product sent to wrong address or destination.
PARTS/ COMPONENTS	Packaging materials Accessories Mechanical parts Electronic parts Electrical parts	Defective Materials	Material entering process is defective or inadequate for the intended function, process, or purpose.

Class of Non-conformance			Parts/ Components	Information					Process												
Particular	Part	Item	Defective material entering	Ambiguous information	Incorrect information	Mismeasurement	Omitted information	Inadequate warning	Misaligned parts	Misadjustment	Added material or part	Prohibited act	Omitted operations	Omitted part	Counting errors	Wrong material	Wrong destination	Wrong location	Wrong operation	Wrong part	Wrong orientation
Safety	Label	Carton box			◉		◉	◉													
		Plastic wrapper			◉		◉	◉													
		Rear Panel			◉		◉	◉										◉			
	Electrical	Power Cord	◉	○				○								◉				◉	○
		Wire Harness	◉						◉		◉			◉		◉			○	◉	◉
		Cord Clamp	◉							○				◉		◉		○		◉	◉
		Tie Band	◉						◉	○	◉	○	◉	◉	○	◉	○	◉	◉	◉	◉

Legend: ◉ high probability ○ low probability

Figure 5-10 Mistakes related to product safety

Besides the checklist, other documents such as regulations, guidelines, drawings, instructions, engineering change orders, and bills-of-materials are also referred to and compared when inspecting the product and the trial-run. For example, in the safety regulations imposed in the United Kingdom under the General Product Safety Regulation (DTI, 2005), Section 3.3 states, "*The safety of a product will be assessed having regard to a number of matters and, in particular:*

- *the product's characteristics;*
- *packaging;*
- *instructions for assembly and maintenance, use and disposal;*
- *the effect on other products with which it might be used;*
- *labelling and other information provided for the consumer; and*
- *the categories of consumers at risk when using the product, particularly children and the elderly.*"

To comply with the Regulation, the Engineering team will check whether there are non-conformances with the safety aspect of assembly as required by the Safety Regulation. The Production team inspects all safety parts/components assembled in the product, and that the assembly configurations are free from non-conformances. Figure 5-11 illustrates the identification of non-conformances in the product safety item. The validation team inspects the safety label or certification markings, based on a checklist, against the product. The evidence of non-conformance is the missing label (as demonstrated in Case 1 in Chapter 3) alleged as an omitted information mistake, and this is classified under *Information Non-conformance*. Since the safety label is part of the safety regulation (which is an information aspect of the product), this non-conformance is thus an *Information Non-conformance,* according to the PNC.

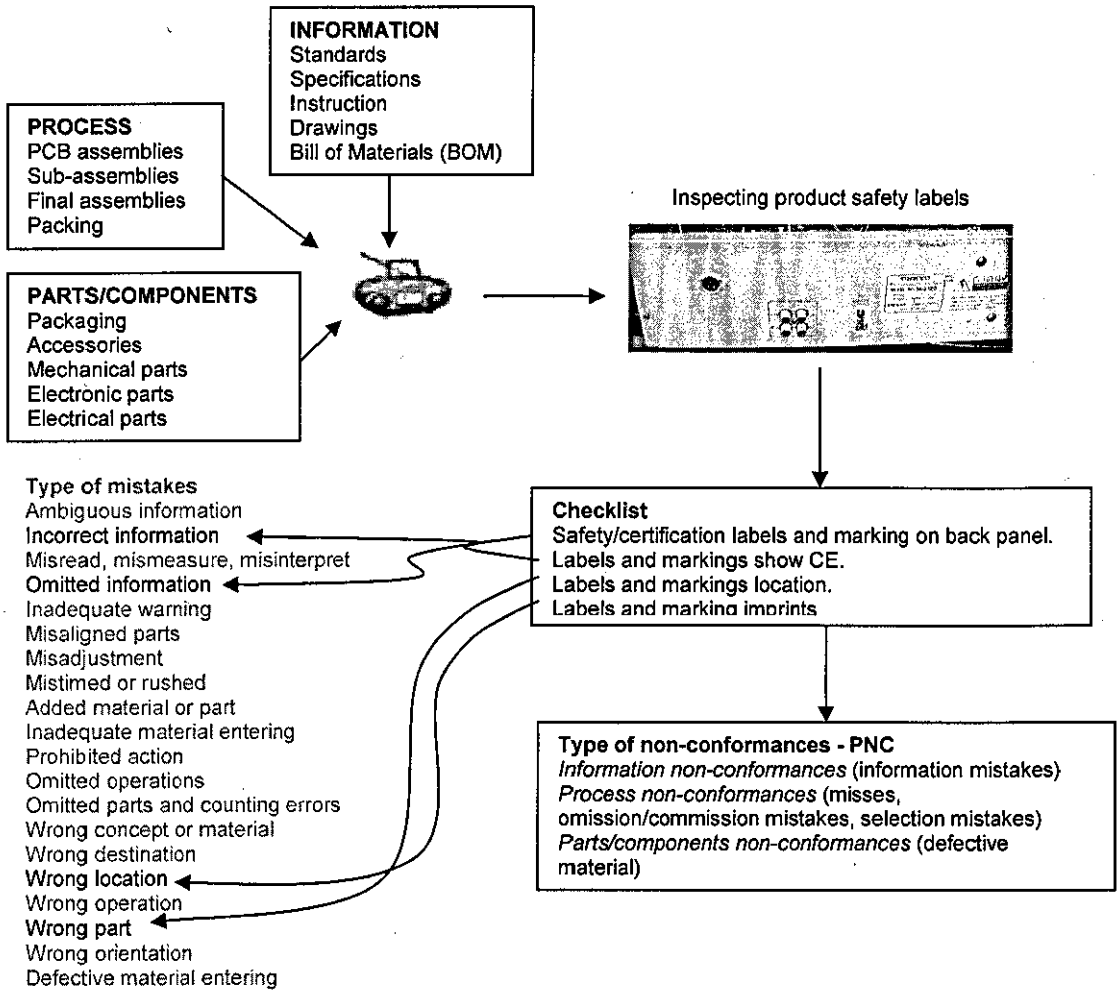


Figure 5-11 Identifying non-conformances in product safety label

The next section explains the second activity in Step 2 – Detection which is the task of logging the non-conformances identified in the Phases 1 and 2 inspections.

5.3.4.3 Logging inspection results

The logging of identified non-conformances is a straightforward task. Throughout the inspection, the validation team records and logs the evidence of non-conformances marked in the checklist, and into an electronic form, namely the Inspection Summary Form (a paper-based example of the structure of the form is given in the workbook in Appendix B, page 25). The structured of the electronic form consists of

- general information about the product under validation – the product reference, date of inspection, the inspector's identification, inspection document/checklist reference.
- description about the inspection task – either the product (Phase 1) or the trial-run (Phase 2), and other specific particulars of the product's characteristics.
- spaces for filling-in the information about the non-conforming items and the mistakes, as dictated in the checklist.
- supplementary information related to the mistakes, type of non-conformances, and non-conformance consequence and solution description.

The data in the electronic inspection summary form can be processed to produce a report according to the inspection activity, particulars of inspection, the location of inspection, item inspected, description of the non-conformances, and type of mistake. However, companies may have their preferences in designing their own inspection form. Step 2 – Detection is completed under two conditions:

1. If non-conformances are not identified, either in the product or trial-run, then proceed to Step 5 – Verification.
2. Identified non-conformances are subject to scrutiny in Step 3 – Analysis.

In this step, mistakes are identified on the product and in a trial-run based on the checklist describing the tangible or potential mistakes. The example has shown that non-conforming items are due to one or many mistakes. These non-conformances are grouped into three classes: Information non-conformances, Process non-conformances, and Parts/components non-conformances, according to the PNC. Non-conformances identified and recorded in the Inspection Summary Form are analysed and presented, using the NoCoS matrix. The next section describes Step 3 – Analysis and the deployment of the NoCoS methodology.

5.3.5 Step 3 – ANALYSIS

The *purpose* of the analysis is to define the non-conformances based on the PNC, and determine the severity and solution with the aid of the NoCoS methodology. The analysis *procedure* begins with a meeting of the validation team. In the meeting, the results from Step 2 – Detection are analysed. The analysis *activities* are depicted in bold in Figure 5-12, where the validation team classifies the non-conforming items based on the PNC, and determines the consequence and solution using the NoCoS methodology.

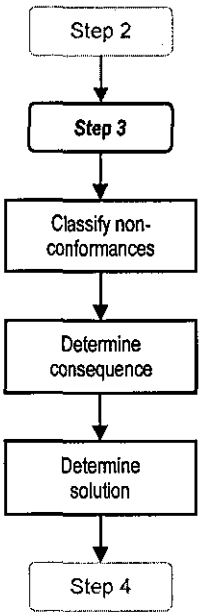


Figure 5-12 Step 3 – ANALYSIS activities flow diagram

In the analysis meeting, any evidence of non-conformances from the product, the trial-run, the checklist used to identify non-conformances, and the Inspection Summary Form which contains the report of non-conforming items are scrutinised to determine

- class of non-conformance
- consequence level
- solution condition

Then the results of the analysis are logged into the *NoCoS matrix*. The outcome of the analysis is complete information about the product's non-conformances pertaining to

1. non-conforming items,
2. class of non-conformances and type of mistakes, and
3. consequence and solution of non-conforming items.

The analysis meeting is vital in understanding the product's non-conformances, and subsequently learning from the mistakes.

5.3.5.1 Determining class of non-conformances

Information about the non-conforming product is retrieved from the Inspection Summary Form after completing Step 2 – Detection. Based on the PNC, the non-conformances which result from mistakes are classified according to information non-conformance, process non-conformance, and parts/components non-conformance. A non-conforming product may have several manifestations of mistakes, and therefore may acquire one or all three classes of non-conformances. An example of a non-conforming product is shown in Figure 5-13, where the mistakes are identified in four items of the certification label, shown in bold. In the inspection form, the validation team determines that the non-conforming items correspond to two classes of non-conformance: Information Non-conformance and Process Non-conformance, which are coded IN and PR, respectively. Parts/components non-conformance is not applicable, therefore it is struck off. In the inspection form, all non-conforming items are listed with the types of mistake explicitly identified, and classified categorically according to the classes of non-conformance. Consequently, these data can be used to plot the occurrences of the three classes of non-conformances and formulate ways to reduce them (the task of the development team).

Inspection Summary Form

Part	*Description*	*Type*	*NC*	*CON*	*SOL.*
Cert. Label	**1. label omitted**.....	**OMI**	**IN / ~~PR~~ / ~~PC~~**	.....	.....
.....	**2. CE marking incorrect**	**INI**	**~~IN~~ / PR / ~~PC~~**	.....	.....
.....	**3. label location incorrect**.....	**WRP**	**~~IN~~ / PR / ~~PC~~**	.....	.....
.....	**4. label print inadequate**.....	**AMI**	**IN / ~~PR~~ / ~~PC~~**	.....	.....

Note: NC = non-conformances

Figure 5-13 Logging classes of non-conforming items

5.3.5.2 Determining consequences of non-conformances

The consequence of the non-conforming items is determined based on the NoCoS methodology, which corresponds to the implications for product's safety, producibility, and customer perception, as shown in Figure 5-14. The validation team decides which non-conforming item qualifies for a particular type of consequence and assigns a related consequence level code (C1, C2, C3, C4 and C5) into the Inspection Summary Form.

Consequence Level	**C1 :** non-conformance with **safety** standard and requirement. **C2 :** non-conformance that results in a **not producible**. **C3 :** non-conformance that results in a product that can be produced but with big problems or will not be accepted by a **critical** customer. **C4 :** non-conformance that results in a product that can be sold or produced with **minor** difficulties. **C5 :** non-conformance **accepted** by management – no activities will be started to reduce or eliminate this problem (considered as a non-problem).

Figure 5-14 Non-conformance consequence coding and description

Again, in the example of non-conforming product safety shown in Figure 5-15, the non-conforming certification label is very severe as it concerns a safety regulation requirement. Therefore, the consequence is determined and logged as level C1 in column CON (Consequence), shown in bold. Later, the validation team will identify which item should be the priority and warrant immediate action.

Inspection Summary Form

Part	*Description*	*Type*	*NC*	***CON***	*SOL.*
Cert. Label	**1. label omitted**.....	OMI	IN / ~~PR / PC~~	**C1**	.....
.....	**2. CE marking incorrect**	INI	~~IN~~ / PR / ~~PC~~	**C1**	.....
.....	**3. label location incorrect**.....	WRP	~~IN~~ / PR / ~~PC~~	**C1**	.....
.....	**4. label print inadequate**.....	AMI	IN / ~~PR / PC~~	**C1**	.....

Note: CON = Consequence Level

Figure 5-15 Logging consequence type on non-conforming items

5.3.5.3 Determining non-conformance solution

The NoCoS methodology describes non-conformance solutions either as known or unknown, as shown in Figure 5-16. The known solution has three types, coded as S2, S3 and S4 in column SOL (Sequence). The unknown solution - S1, implies that new non-conformances appeared which needed solution, and were then added to the company's database.

Solution Status	**S1** : solution not known **S2** : solution known but not yet positive **S3** : solution known but not yet introduced **S4** : solution known and introduced

Figure 5-16 Non-conformances solution coding and description

The validation team identifies which items already have the solutions, and vice versa, assigns a solution status code, and logs them on the Inspection Summary Form. Using the example of the non-conforming product safety, as shown in bold in Figure 5-17, item 1 has solution status S4, items 2 and 3 have similar solution - S3, and item 4 has solution S2 which requires more time to develop. The condition of the solutions determines the rapidity in rectifying non-conformances. Hence, the validation team can immediately identify the appropriate course of action for the non-conforming items.

Inspection Summary Form

Part	*Description*	*Type*	*NC*	*CON*	***SOL***
Cert. Label	**1. label omitted**.....	OMI	IN / ~~PR / PC~~	C1	**S4**
.....	**2. CE marking incorrect**	INI	~~IN~~ / PR / ~~PC~~	C1	**S3**
.....	**3. label location incorrect**.....	WRP	~~IN~~ / PR / ~~PC~~	C1	**S3**
.....	**4. label print inadequate**.....	AMI	IN / ~~PR / PC~~	C1	**S2**

Note: SOL = Solution Status

Figure 5-17 Logging solution status on non-conforming items

5.3.5.4 NoCoS Matrix

The application of the NoCos matrix is straightforward. The matrix is used to log the non-conformance coded data which have been narrowed down into two aspects:

Consequence Level and Solution Status. From the Inspection Summary Form, the accumulated coded data are transmitted into the appropriate cells of the matrix. As shown in Figure 5-18, in the inspection form, the coded data in CON (C1) and SOL (C1S4, C1S3 and C1S2) show four results, of which two have the same codes to be transmitted into the NoCoS matrix. The accumulated data are placed in the related cells, shown in bold in Figure 5-19.

Inspection Summary Form

Part	*Description*	*Type*	*NC*	***CON***	***SOL***
Cert. Label	**1. label omitted**.....	OMI	IN / ~~PR / PC~~	**C1**	**S4**
.....	**2. CE marking incorrect**	INI	~~IN~~ / PR / ~~PC~~	**C1**	**S3**
.....	**3. label location incorrect**.....	WRP	~~IN~~ / PR / ~~PC~~	**C1**	**S3**
.....	**4. label print inadequate**.....	AMI	IN / ~~PR / PC~~	**C1**	**S2**

Notes: CON = consequence level; SOL = Solution Status

Figure 5-18 Consequence and solution data of non-conforming items

		Non-conformance Consequence Level				
		C1	C2	C3	C4	C5
Solution Status	S1					
	S2	**1**				
	S3	**2**				
	S4	**1**				

Figure 5-19 Accumulated non-conformance results in NoCoS matrix

The NoCoS matrix provides valuable data by visualising all the product's non-conformances which are very crucial in measuring the performance of the product under validation in terms of:

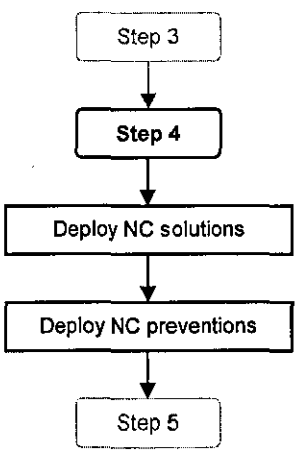
- occurrence of mistakes and non-conformances.
- consequences and solutions condition.

The matrix can also be translated into a statistical report required in problem-solving and decision-making activities in the product development processes. Step 3 – Analysis is complete when all identified non-conforming items have accurate descriptions on the type of mistakes, and the class of non-conformance, and are prioritised according to the consequences and solutions.

In summary, in the analysis meeting, the inspection checklist and the physical evidence of the non-conformances provide the input for the NoCoS matrix (see Figure 5-18). The Inspection Summary Form contains the data on non-conforming items with unique codes related to the class or classes of non-conformances, the type of consequence, and the solution to the non-conformances. These data, which represent the outcome of the Step 2 – Detection and Step 3 – Analysis, are transmitted into the NoCoS matrix. The next step is the rectification of the non-conformances based on the results tabulated in the NoCoS matrix.

5.3.6 Step 4 – Rectification

The mistake-correcting process follows four stages: (1) identifying the occurrences of the mistakes, (2) reporting, (3) rectifying or correcting, and (4) preventing the mistakes (Stevenson, 1996; Sasou and Reason, 1999). Items (1) and (2) have been employed in Steps 2 and 3, respectively. Step 4 – Rectification is the actual correction and prevention of mistakes which caused non-conformances. If these are not corrected and prevented, they will recur and escape to production. The *purpose* of the rectification step is to implement the solution and prevention of non-conformances. The rectification *procedure* continues from the analysis meeting. In the meeting, the solution and prevention of non-conformances are determined and deployed. The rectification *activities* are shown in bold in Figure 5-20, in which the validation team deploys the solution, followed by formulating and implementing the prevention plans.



Note : NC = non-conformances

Figure 5-20 Step 4 – RECTIFICATION activities flow diagram

5.3.6.1 Deploying solutions

Continuing the meeting from Step 3, the second agenda item is to plan rectification of the non-conformances. The validation team discusses the deployment of the solutions for each non-conforming item listed in the Inspection Summary Form. Based on the NoCoS methodology, non-conforming items with the most severe consequences (C1) and known solutions (S2, S3 and S4) are the highest priority; however, items with known solutions can be deployed promptly. The design team deploys the rectification regarding design and documentation, whilst the engineering and production team ensures the correct execution of the solution.

For example, the non-conforming safety label has a known solution which is by illustrating the correct label in the assembly drawings and work instructions, where the illustration represents the actual graphic of the label. This solution can be deployed immediately into the appropriate assembly drawings and work instructions. Hence, the mistake of the missing label can be avoided when both items and the drawings tally. For non-conforming items with unknown solutions, finding the solution is best if it comes from the members of the validation team, as each member contributes from different perspectives, whilst working on the improvement to the items is the design team's responsibility.

5.3.6.2 Deploying preventions

In the industry, solutions are divided into two types: permanent and temporary. The permanent solution is implemented in the subsequent improvement to the product, whilst the temporary solution is deployed on the initial batch of production. However, the solution does not guarantee that non-conformances will not recur. For example, the case of the protective pads described in Chapter 3 Section 3.3.1, where the operator forgets to fix the pad during production, although the temporary solution is deployed. Therefore, an *extensive prevention plan*, which is the third rule of the validation process, is to be formulated to avoid mistakes from recurring.

The way of preventing recurrence of mistakes is either by improving the product, process and parts/components in the next version, or by employing the approaches such

as mistake-proofing, as described in Chapter 2. The principles of mistake-proofing (Shingo, 1986; Hinckley, 2001) are:

- *make it easier to discover problems that occur.*
- *make wrong actions more difficult.*
- *make incorrect actions correct.*
- *make it possible to reverse actions - to 'undo' them - or make it harder to do what cannot be reversed.*

To illustrate the deployment of the solutions and preventions for non-conformance, the example of the missing part is shown in Figure 5-21.

Other prevention examples based on the mistake-proofing approaches are shown and illustrated in Annexes 4 and 5. Although the best prevention is by building quality and prevention of non-conformances into a product during the design stage, the prevention strategy should however be prepared earlier, before production, to reduce the drawback at later stage.

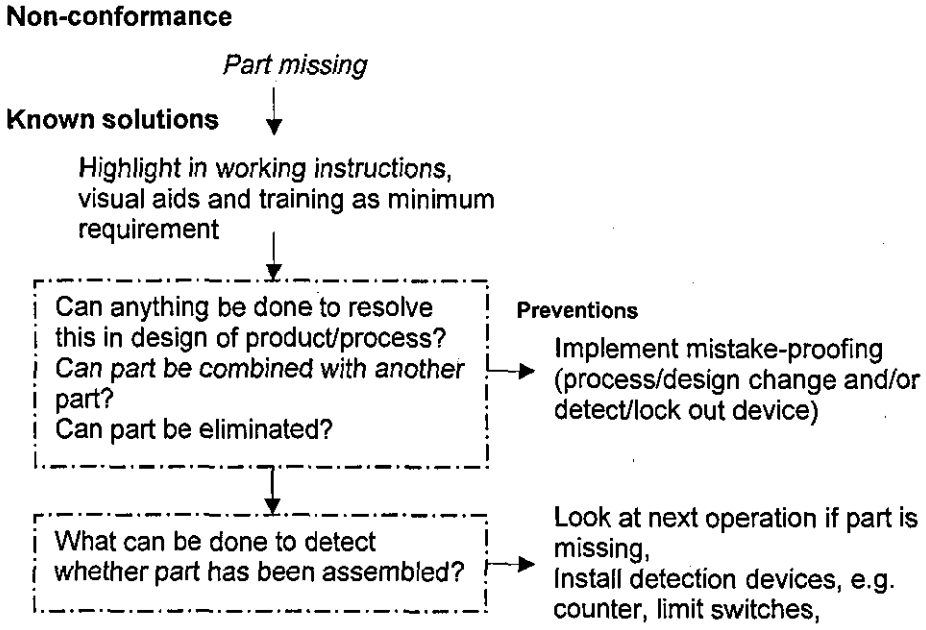


Figure 5-21 Deploying solutions and preventions

The final step of the validation process is Step 5 – Verification, in which, upon completion of the four steps, the validation team collectively decide that either the product can proceed to full production or requires revalidation.

5.3.7 Step 5 – VERIFICATION

As quoted by Alexander and Clarkson (2002), *"Verification is a process that occurs within each of the device design, process design, and production development activities, and provides a means for answering the question: Are we building the thing right?"* The *purpose* of the verification meeting is thus to verify that the product and trial-run are completely inspected, non-conformances are defined and rectified appropriately, and that the product has been rigorously validated. The verification *procedure* begins with a meeting of the validation team to confirm that Steps 1, 2, 3 and 4 are deployed and documented appropriately. The initiation *activities* depicted in bold in Figure 5-22 centre in a meeting where the validation team carry out

1. inspection verification on the product having no evidence of non-conformances,
2. rectification verification after the non-conformances are corrected and prevention plans are deployed, and
3. documentation.

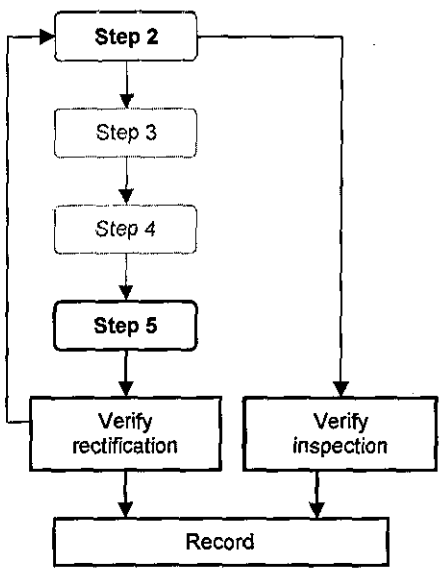


Figure 5-22 Step 5 – VERIFICATION activities flow diagram

5.3.7.1 Verifying inspection and rectification

In the verification meeting, the validation team decides

- to *accept* the product for full production, since there is no evidence of non-conformances in the product's information, process, and parts/components, and therefore no further validation activity is required;
- to *conditionally accept* the non-conforming product, on condition that the product and trial-run have been corrected, and the prevention plan has been deployed; however, the product is to be re-inspected.

5.3.7.2 Documenting validation process

The whole conduct and outcome of the validation process are compiled and documented to build up the repository or database of non-conformances, the problem-solving activities, and to improve the product and validation process in future product developments. Documenting the validation process includes the deployment of the PNC and the NoCoS methodology. The verification meeting results in awareness of the mistakes, solutions and preventions for the product under validation. This allows the opportunity for sharing the experience and information, and learning across different product ranges and organisational functions. This is another only way for an organisation to 'learn' from the mistakes, exercising total conformance and practising continuous improvement.

Step 5 – Verification is completed after all the validation team sign the 'memorandum of agreement' (MOA) in certifying that the validation has been conducted with complete rigour and deploying the decisions agreed upon collectively.

5.4 IMPROVED VALIDATION PROCESS

This section compares current methods with the improved validation process. The five-step validation process described in this chapter is similar to what has been practised in

the industry. However, this research has introduced new approaches in identifying non-conformances in Step 2, and controlling non-conformances in Step 3.

5.4.1 Approach in identifying non-conformances as the result of mistakes

Whilst the current practice (Peters et al., 1999; Ulrich and Eppinger, 2003; Karapetrovic and Wilborn, 2002) adopted the method of identifying product conformances against the specification and quality requirements, this research in contrast, subscribes to a method of identifying the product's non-conformances by inspecting the potential mistakes associated with the item being validated. As described in Section 5.3.4.2, the checklist illustrates the attributes of non-conformances, accurately based on the type of mistakes. This approach is possible with the new non-conformance classification of Product-based Non-conformance or PNC, introduced in Step 2 in the validation process.

The work of Hinckley (2001) has contributed to the understanding of the classification and type of mistakes in production, which is significantly relevant in identifying and classifying non-conformances in pre-production (described in Chapter 4). He identifies various mistakes in production and groups them into five generic classifications of the Outcome-based Classification, as described in Chapter 2, Section 2.4.3. However, this research has found that these mistakes are correlated with the three product characteristics of information, process and parts/components. The non-conformances manifested in the product which are due to mistakes, therefore, can be grouped in relation to the three characteristics. Hence, this research has introduced a new non-conformance classification, the PNC (Information Non-conformances, Process Non-conformances, and Parts/components Non-conformance), (see Table 5-2, Section 5.3.4.2), which has been incorporated into Step 2 of the product validation process.

5.4.2 Approach in Controlling Non-conformances with Consequences and Solutions

Companies analyse non-conformances typically using the Failure Mode and Effect Analysis (FMEA) (Chao and Ishii, 2003; Stamatis, 2003) and Simple Severity Ranking (SSR) (Winchell, 1996; Ghinato, 1998). While the former applies a complex equation,

the latter has a vague description in defining non-conformances (see Chapter 2, Section 2.4.4). Although both methods view non-conformances from the same perspective of customer perception and producibility, these methods describe only the severity of the non-conformances, leaving the task of formulating the solution separate. The new approach introduced in Step 3 of the validation process also views non-conformances alike; however, contrary to the two methods, the new approach describes non-conformances, not only with the severity but with the solutions as well, and this approach is easily quantifiable. The approach is called the Non-conformance Consequence and Solution or NoCoS methodology which determines non-conformances based on the non-conformance consequences and non-conformance solutions (see Section 5.3.5).

As mentioned previously in Chapter 4, Section 4.2.2, companies should already have vast information on the consequences and solutions for a particular non-conformance. Using this information, companies can rapidly deploy the corrective actions and control in pre-production to prevent non-conformances from escaping into production.

Table 5-3 compares the characteristics of the two common methods used to analyse non-conformances against the NoCoS methodology which proves to be superior. The NoCoS methodology is capable of identifying the occurrence, defining the severity, describing the solutions, and measuring the non-conformances, and it is simple to execute.

Table 5-3 Comparing methods of analysing non-conformances

Method	*Occurrence*	*Severity*	*Solution*	*Quantifiable*	*Simplicity*
FMEA	✓	✓	-	✓	-
SSR	-	✓	-	-	✓
NoCoS	✓	✓	✓	✓	✓

The NoCoS methodology was developed by adapting the work of Yuan (2002), as described in Chapter 4, Section 4.3.3.1. Whilst the work focuses on controlling product reliability problems throughout the product development process, this research has used the method in controlling product non-conformance in the pre-production stage, and in particular, in Step 3 of the product validation process.

5.5 SUMMARY

This chapter has explained how the new approaches to identify and control non-conformances are adopted in the product validation process in pre-production. A product validation workbook formulated to provide a step-by-step guide to the way these approaches are put into operation has been explained. The structure of the workbook has been described, the validation process framework has been illustrated, and the conduct or sequence of the validation activities has been explained.

Understanding the three product characteristics and the type of mistakes corresponding to each characteristic enables effective and rapid identification of potential non-conformances, classified as the PNC. The PNC provides important information to enable reducing of non-conformances and increasing of product conformances during the development process. The NoCoS methodology is capable of delivering a rigorous analysis of the non-conformances, and facilitates rapid deployment of the solutions and extensive prevention of the non-conformances. The current method lacks the capability to provide a holistic approach to identify, analyse, solve, and prevent non-conformances in pre-production. Both the PNC and the NoCoS methodology enable understanding of product non-conformance and quality deficiencies, and hence learning from mistakes.

Evaluation of the concepts of the PNC and the NoCoS methodology has been conducted. The next chapter discusses the evaluation of the new approaches in the product validation process, in terms of practicability for manufacturing industry.

CHAPTER 6

EVALUATION OF NEW APPROACHES: EXPERTS ASSESSMENT

6.1 INTRODUCTION

This chapter presents the evaluation of the concepts of the new approaches in identification and control of non-conformances, as described in Chapter 4, and its deployment through a workbook for improved product validation, as described in Chapter 5. The evaluation through expert opinion assessing the potential of the new approaches for pre-production is conducted in two phases: Phase 1 evaluating the concepts, and Phase 2 evaluating the deployment.

Three main sections are contained in this chapter. Section 6.2 describes the evaluation approach. Section 6.3 presents the evaluation results of the two phases. Section 6.4 discusses the evaluation results and evaluation approach.

A discussion on the development, deployment, and evaluation of the new approaches followed by the conclusion and future work of this research is presented in the next chapter.

6.2 EVALUATION APPROACH

6.2.1 Aim and Objectives of Evaluation

The aim of the evaluation was to establish the potential of the new approaches for improved product validation in pre-production. To achieve this aim, opinions from experts in the development of consumer electronic products are sought with the following evaluation objectives:

1. To determine the relevance and comprehensiveness of new approaches in addressing product non-conformance in pre-production.
2. To assess the coherence and capability of the new approaches in identifying and controlling non-conformances during product validation.
3. To assess the feasibility with which the new approaches can be put into practice.
4. To improve the new approaches and validation process from comments and recommendations.

The research has adapted an evaluation approach described in the following section.

6.2.2 Significance of Evaluation

According to Patton (1982) cited in Noble, (1999), evaluation is defined as,

> "*... a systematic collection of information about the activities, characteristics, and outcomes of programs, personnel, and products for use by specific people to reduce uncertainties, improve effectiveness, and make decisions with regard to what those programs, personnel, or products are doing and affecting*".

Evaluation plays an important role to acquire and assess information with the aim to provide a sensible response about a programme (Trochim, 2006). It is an analysis oriented towards improvement, thus it is part of a continuing process until successful completion of the programme, in conjunction with Deming's PDCA or the Plan-Do-Check-Act cycle (Deming, 1986; Elshennawy, 2004). In addition, evaluation helps to identify ambiguity, anomalies, and to convince users that the programme is correct and has been built correctly (Alexander and Clarkson, 2002). Hence, the significance of having expert evaluation, among others, is to (DeVellis, 1991)

- *confirm or disconfirm the definition of the programme under study*
- *determine the relevance of each component in the programme*
- *evaluate the clarity of each component*
- *evaluate the conciseness of each component*
- *point out what has not been included in the programme*

In the context of this research, evaluation is to assess the research ideas by experts from manufacturing industry, and to make judgement of the practical contribution of the ideas. Thus, the final stage of this research is evaluation of the new approaches in the product validation process in pre-production.

6.2.3 Types of Evaluation

There are two types of evaluation: formative or improvement-oriented, and summative or judgement-oriented (Patton, 1994, 1996; Scriven, 1996, Trochim, 2006):

- Formative evaluation's main purpose is programme improvement to achieve a higher degree of goal accomplishment. This evaluation facilitates the programme by improving it, provides responses on strengths and weaknesses that may affect goal attainment, and prepares for summative evaluation (Patton, 1994; Wholley, 1996).

- Summative evaluation determines that the improved programme being deployed qualifies for *merit and worth,* and that goals have been accomplished. "*It is evaluation done for, or by, any observers or decision makers who need evaluative conclusions for any reasons besides development*" (Scriven, 1991, cited in Patton, 1996).

Hence, it can be seen that formative evaluation is for evaluating a programme under development and improvement, while summative evaluation is for evaluating a programme which is fully developed and implemented, or sometimes called post-implementation evaluation (Mohamed, 2006).

6.2.4 Combined Evaluation

The new approaches to be deployed in pre-production are in a sensitive setting and related to critical operation in companies. Companies' pre-production involves confidential activities, such as new product introduction, product improvement, prototyping, and product validation, and thus they are reluctant to allow the new ideas

to be implemented and tested in the companies. However, when testing cannot be carried out for legitimate circumstances, which is not unusual in evaluation of organisational methodologies and tools, other valid evaluation methods may be adopted (Brookes et al., 2000); in this situation, expert evaluation through interviews and combining both formative and summative evaluations are adopted.

The concepts of the new approaches are assessed through formative evaluation by experts through interviews (Robson, 1993, cited in Brookes et al., 2000). Here, new approaches are evaluated by highly experienced experts working in a wide range of companies in manufacturing industry, who have authority and are currently involved in the subject being addressed. As a result, maximum validity of the concepts of the new approaches is achieved since it is viewed from a practical and real environment, and from various companies. The deployment and applicability of the new approaches in the improved product validation process are then assessed with summative evaluation. The evaluation involves interviewing a group of experts from different functions, in one company, responsible for the product validation. The combined evaluations have been carried out in two phases, as shown in bold in Figure 6-1.

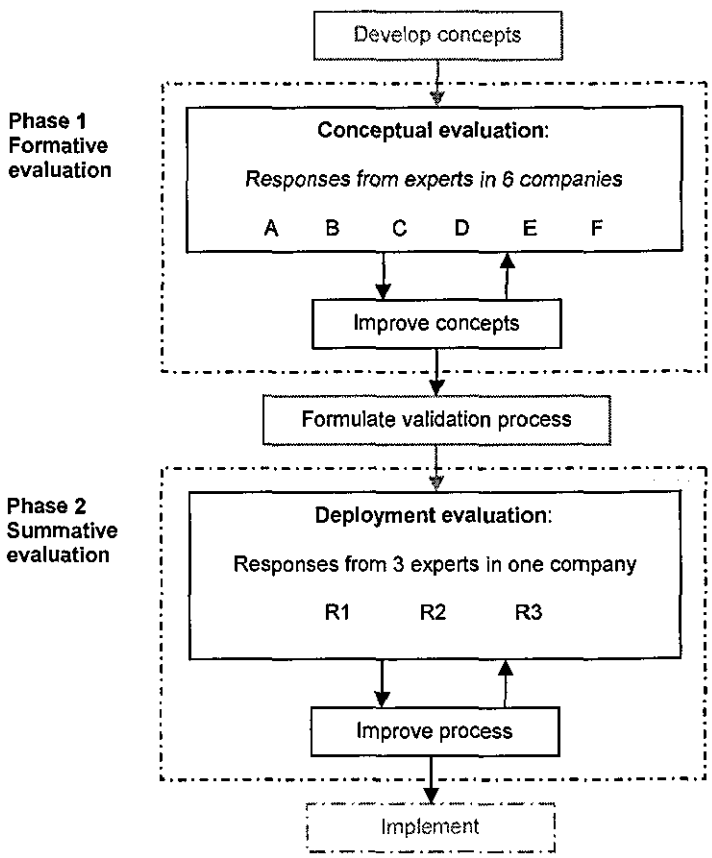


Figure 6-1 Phases 1 and 2 evaluations

In Phase 1 formative evaluation, experts (in managerial position and involved in pre-production) from various companies evaluate the concepts of PNC and NoCoS methodology. From the responses of this evaluation, suggestions for improvement are anticipated and to be deployed into the product validation process.

In Phase 2 summative evaluation, experts who conduct product validation from different functions in one company, evaluate the validation process where the concepts of PNC and NoCoS methodology are deployed. The evaluation sought to determine ease of deployment, coherence and comprehensiveness when introduced in an actual setting. The overall concepts and validation process are improved and fine-tuned to produce a final product validation methodology based on the responses of this evaluation.

The new approaches could not be said to improve product development performance with certainty; however, from this evaluation *"conclusion could be drawn on whether the user of the new approaches thought that it would"* (Brookes et al., 2000).

6.2.5 Selecting Companies and Evaluators

To evaluate the new approaches, experts from ten major multinational companies which design and produce a wide range of consumer electronic products were invited to participate. These companies were contacted personally through telephone and e-mail. Six companies agreed to participate in Phase 1 evaluation, and one of them also agreed to participate in the Phase 2 evaluation. The companies requested to be anonymous when reporting the evaluation in this thesis. Thus, experts representing these companies were identified as A, B, C, D, E and F. The profile of evaluators, by designation, length of service, and of companies participating in the evaluation is shown in Table 6-1.

Table 6-1 Profile of evaluators and companies

Company	Evaluator Designation	Years in company	Product	Product type	Company's origin
Phase 1 evaluation – Evaluators and companies					
A	Senior Engineer (NPI Division)	6	Hard disk drives for computers, mobile devices and enterprise storage.	OEM	America
B	Assistant Manager (R&D Department)	11	CRT TV, LCD TV, projector and computer monitors	Finished product	Japan
C	Senior Manager (R&D Division)	13	CRT & electron devices	Finished product	South Korea
D	Senior Engineer (R&D Centre)	7½	Hi-fi, radio cassette recorders & home-theatre	Finished product	Japan
E	Executive (Engineering/NPI Department)	4	Car air conditioners, radiators, and engine electrical control units.	OEM	Japan
F	Senior Manager (Supply Chain/NPI Division)	20	2-way radio, mobile phone	Finished product	America
Phase 2 evaluation - Evaluators and company					
D	Senior Engineer (R&D Centre)	7½	Hi-fi, radio cassette recorders & home-theatre	Finished product	Japan
	New Product Coordinator (Engineering Department)	10			
	Assistant Engineer (QA Department)	5			

Notes: R&D = Research and Development NPI = New Product Introduction QA = Quality Assurance
OEM = Original Equipment Manufacturer

6.2.6 Conducting Interviews

Interview requires the interviewees to provide answers and information to a pre-set schedule of questions (Fauladi, 1999). Interviews may be conducted individually or in group, and face-to-face or by other means such as the telephone, Internet chatting, and video conferencing. The advantages of interviews, among others, include:

- ability of interviewee to ask for clarification
- ability to ask interviewee to provide additional information
- ability of interviewee to volunteer additional information

Responses from interviews are normally hand-noted or tape-recorded, which are later transcribed and then analysed. However, the limitations with interviews are time, effort, and expense involved in arranging interviews, conducting interviews, and in transcribing and coding interview transcripts.

In the context of this research, interviews attempt to seek evaluators' opinion about the new approaches on (Mohamed, 2006),

- what the evaluator liked about the new approaches
- what the evaluator thought would work
- what the evaluator thought would not work in an industrial setting

In Phase 1 evaluation, six interview sessions were conducted individually, in which each session lasted approximately between 2 and 2½ half hours. Phase 2 evaluations took approximately 3 hours, conducted in a group which involved three evaluators from the same company. Evaluators were selected from persons directly involved in product validation processes in pre-production. The interview sessions were strictly monitored within the allocated time, as they took place in evaluators' working hours.

Although schedules of questions were given earlier to evaluators, certain aspects of the new approaches were elaborated during the interviews for clarification. This is because evaluators did not all understand the principles underlying the concepts being introduced.

By agreement of participants, interviews were tape-recorded throughout the session and then transcribed for analysis. Transcription summaries of Phases 1 and 2 interviews are given in Appendices C2 and D2, respectively.

6.2.7 Designing Schedule of Questions

The schedule of questions was based on the evaluation objectives as stated in Section 6.2.1. In general, the questions required evaluators' own *perceptions, criticism,*

comments, and *suggestions* about the topic being addressed (Yusof and Aspinwall, 2001). Question items were in both close and open-ended format. In close-ended questions, evaluators needed to reply either 'Yes', 'No', 'Not sure', or 'Don't know', on five aspects:

- *Relevance* – the concepts deliver the intended purpose and provide appropriate solutions (JICA, 2007) in identification and control of non-conformances.
- *Comprehensiveness* – the concepts take into account relevant or major aspects (Heerkens, 2003) in addressing non-conformances.
- *Coherence* – the concepts consists of elements which present logical association and integrity or fit together (Thagard, 2007) to apply in product validation.
- *Practicality* – the concepts are implementable, in terms of ease of understanding and having potential of use by people involved in validation of the pre-production.
- *Recommended* – the concepts are useful and implementation will benefit the company's product development and validation process in pre-production.

In open-ended questions, evaluators provide opinions, comments and additional information.

The schedule of questions in Phase 1 is divided into four parts, as shown in Table 6-2. Part A is about evaluators and companies (see Table 6-1, Section 6.2.5), and Part B relates to information about companies' pre-production practices. Part C, shown in bold, will be presented in the following sections as evaluation results. A conclusion is for additional information and comments. Examples of the schedule of questions for Phase 1 are given in Appendix C1.

Table 6-2 Phase 1 Evaluation – summary of questions

Items	*No. of questions*	*Purpose*
Company-related:		
PART A Panel and company profile	3	General information about evaluator and company
PART B Pre-production practices Validation process Product non-conformance	14	Brief description on conduct of pre-production, product validation practices, and managing non-conformances.
Concepts evaluation:		
PART C **Validation process** **Concepts of identification and control of non-conformances** **Tools and techniques**	**6**	**Perception: relevant, covering all major aspects of non-conformances and validation process, sensible approach.** **Acceptability: feasible, ease of implementation, simple, practical, comprehensive, uncomplicated.**
CONCLUSION	2	*Additional information*

It should be noted that the schedule of questions for Phase 1, in Appendix C1, consists of seven items. Due to time constraint in interviews sessions, item Q C6 was omitted. This question did not affect the aim of the evaluation. The question is related to mistake-proofing as a prevention strategy, and since this is an established approach, absence of a response has effect less on the evaluation. Hence, only six items were addressed to evaluators; likewise, six results are reported in this thesis.

The schedule of questions in Phase 2 is also divided into four parts, as shown in Table 6-3. Part A is about evaluators and companies already shown in Table 6-1, Section 6.2.5. Parts B, C and D are questions about evaluators' perceptions on the concepts of non-conformances introduced, practicability of the new approaches, and appropriateness of the improved validation process presented in the workbook. Examples of the schedule of questions for Phase 2 are given in Appendix D1.

Table 6-3 Phase 2 Evaluation – summary of questions

Items	*No. of questions*	*Purposes*
Company-related:		
PART A Panel and company profile	3	General information about panel and company background.
Process evaluation:		
PART B **Appropriateness of non-conformances concepts**	**3**	**Perception: relevant, covering all major aspects of non-conformances and validation process, sensible approach.**
PART C **Practicability of new approaches**	**5**	**Acceptability: feasible, ease of implementation, simple, practical, comprehensive, uncomplicated.**
PART D **Appropriateness of workbook**	**3**	

To ensure smooth running of interview sessions, accurate responses, and shorter time, the schedule of questions was tested in the first company interviewed (company E). The purpose of testing is to identify problems and clarify any items in the questions so that they are free from any ambiguity. Consequently, some questions have been removed, corrected, and simplified. The amended schedule of questions was then used in the following interview sessions in other five companies. The next section presents the results of Phase 1 evaluation.

6.3 EVALUATION RESULTS

6.3.1 Phase 1 Evaluation Results

Six evaluators from six different companies participated in the evaluation. They represent multinational companies which design and produce consumer electronic products. They hold managerial and executive positions, are responsible for a department or division, and have authority in pre-production and the product validation process. The following section presents the results of evaluation which focuses on five aspects: relevance, comprehensiveness, coherence, practicality, and recommendation. Firstly, validating the product characteristics in which the new approaches were developed, followed by evaluation of the new approaches, and finally, the overall perception (transcription of the evaluators' responses is given in Appendix C2.

6.3.1.1 Product validation model evaluation

The first step of evaluation is to establish that the companies' expert follows a validation process which at general level is similar, that will determine that evaluators fully understand the relationship of the new approaches, and how they will be deployed in the product validation process. Hence, similar validation practices in participating companies will ensure similar evaluation and responses. As shown Table 6-4, all six evaluators agreed that the validation model is relevant in illustrating the conduct of the validation process. Five evaluators responded 'yes' on the model's practicality in representing the process, only one responded 'not sure'. The result indicates that the participating companies share a common validation model.

Table 6-4 Results of Phase 1 evaluation on product validation model

Q C1. Would you suggest that the **product validation model**, as shown below, is							
	Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i	relevant to pre-production?	Yes	Yes	Yes	Yes	Yes	Yes
ii	practical?	Yes	Not sure	Yes	Yes	Yes	Yes
		2 items/12 responses (Yes= 11, Not sure = 1)					

Evaluators claimed that the model is basically the same in representing their company's validation process, with different 'operation details'. This is common, since companies have their own operational execution which differs from other companies'. For example, evaluator F suggests *"survey and simulation"* be added to the mechanism, other than inspection and testing. Evaluator B, however, did not respond to the question accurately.

6.3.1.2 Product validation process evaluation

The next step of evaluation is on the validity of the structure of the validation process or procedure which formed part and component of the conceptual validation model. The validation process consists of five steps, where evaluators established commonality of the process with their own, for evaluation to be appropriate. As shown in Table 6-6, evaluators agreed that the structure of the validation process covers the major processes,

relevant and practical in pre-production. Five evaluators confirmed the practicality of each validation step, except evaluator A who was not sure the process had coherence.

Table 6-5 Results of Phase 1 evaluation on product validation process

Q C2. Is the **validation process,** as structured below,							
	Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i	covering all major process of validation?	Yes	Yes	Yes	Yes	Yes	Yes
ii	relevant in pre-production?	Yes	Yes	Yes	Yes	Yes	Yes
iii	coherent?	Not sure	Yes	Yes	Yes	Yes	Yes
iv	practical?	Yes	Yes	Yes	Yes	Yes	Yes
		4 items/24 responses (Yes= 23, Not sure= 1)					

The structure of the validation process has been established, as evaluators verified that the steps are *appropriate*, and with a few operational variations it reflects that of their companies. Only evaluator A was unsure of the coherence of the process, arguing that *"some aspects are not included, such as tooling consideration, cycle time, and testing software and chemical"*, but these aspects are excluded from validation due to their complexity.

6.3.1.3 Product characteristics evaluation

The purpose was to establish the relevance of the three product characteristics which represent the product under validation as the basis for the new non-conformance classification, or PNC. The product characteristics are information, process, and parts/components. As shown in Table 6-6, all six evaluators agreed that the three product characteristics: information, process, and parts/components, are relevant and coherent in the context of pre-production. On comprehensiveness, only evaluator F responded 'no'.

Table 6-6 Results of Phase 1 evaluation on product characteristics

Q C3. Are the **key characteristics** of the product under validation, as shown below,

	Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i	relevant to validation?	Yes	Yes	Yes	Yes	Yes	Yes
ii	comprehensive?	Yes	Yes	Yes	Yes	Yes	No
iii	coherent?	Yes	Yes	Yes	Yes	Yes	Yes

3 items/18 responses (17 = Yes, 1 = No)

Evaluators confirmed the three key product characteristics represent the components of the product under validation. Some suggested additional items to be included, for example software source code and regulations, as part of information. In pre-production, software programming details such as source code are not inspected, and regulations such as the certification compliance (UL, VDE, CE, etc.) have been included under Standards.

Only evaluator B has an *"almost similar approach"* in describing product characteristics. They are known as the three components or *'triangle'*: (1) actual part, (2) drawings, and (3) part number. He is in favour of the three key product characteristics put forward in the new approaches. Evaluator F suggests each item of product characteristics be validated also for its reliability. Since this research focuses on the quality inspection only, reliability testing is not related to the subject being addressed.

6.3.1.4 Product-based Non-conformances Classification evaluation

Next is the evaluation of Product-based Non-conformances Classification or PNC. This new classification of non-conformances is based on three key product characteristics: information, process, and parts/components. These characteristics have been established by the evaluators, as mentioned earlier. As shown in Table 6-7, all six evaluators responded 'yes' to the concept of PNC being relevant in identifying non-conformances in pre-production. They agreed that the classification covers all known non-

conformances during product validation, and the concept is coherent and practical from industry's point of view.

Table 6-7 Results of Phase 1 evaluation on PNC

Q C4. In your opinion, are **the classes of non-conformances (PNC)** related to mistakes, shown below,							
	Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i	relevant in identifying non-conformances?	Yes	Yes	Yes	Yes	Yes	Yes
ii	covering all non-conformances?	Yes	Yes	Yes	Yes	Yes	Yes
iii	coherent?	Yes	Yes	Yes	Yes	Yes	Yes
iv	practical?	Yes	Yes	Yes	Yes	Yes	Yes
							4 items/24 responses (24 = Yes)

In supporting the PNC, evaluators claimed that the concept is *"categorically correct in defining non-conformance"* and simple to understand. The illustration and description of the concept is agreed, and provides a broader view and clearer picture of non-conformances. Evaluator C even admitted to realising the importance of identifying non-conformances during development, and suggested that the PNC is about 'risk management'. To him, 700 items validated with 20 items being non-conforming is not an option.

There is one recommendation made with regard to deploying the new approaches in the actual pre-production setting. That is need for training on the new approaches, not only for personnel involved in product validation, but for the operators in production and also suppliers/vendors. Evaluator F agreed that mistakes cause non-conformances, but perceived other elements also contribute, such as process variation and capabilities.

6.3.1.5 Non-conformance Consequences/Solutions methodology evaluation

Non-conformance Consequences/Solutions (NoCoS) methodology is part of the product validation process. This is an approach to control non-conformances. As shown in Table 6-8, all six evaluators responded 'yes' to the methodology being relevant in

controlling non-conformances and generally covering major consequences and solutions. Whilst other evaluators agreed on its coherence and practicality, evaluator A responded 'no' to the former and 'not sure' to the later.

Table 6-8 Results of Phase 1 evaluation on NoCoS methodology

Q C5. Do you think that controlling non-conformances based on the **consequences and solutions (NoCoS)** is

	Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i	relevant in controlling non-conformances?	Yes	Yes	Yes	Yes	Yes	Yes
ii	covering all major consequences and solutions of non-conformances?	Yes	Yes	Yes	Yes	Yes	Yes
iii	coherent?	No	Yes	Yes	Yes	Yes	Yes
iv	practical?	Not sure	Yes	Yes	Yes	Yes	Yes

4 items/24 responses (22 = Yes, 1 = No, 1 = Not sure)

Evaluators commented on some component of the methodology. On coherence and practicality, evaluator A is in favour of testing the NoCoS methodology in an actual setting; however, she admits that testing new ideas may be difficult in companies. Evaluator B criticised that the item on 'not producible' is too broad, but accepted at conceptual level that 'specific items' is negligible.

Evaluators explained their company approaches in controlling non-conformances. For example, in determining the level of severity, they use colour coding, alphabetical/numerical order, and simple major/minor. Others suggest the NoCoS methodology as another alternative for controlling non-conformances. Evaluators D and E strongly support it after being aware that their current approaches had shown some deficiency, for example ambiguity in determining non-conformances.

Evaluator C viewed the control of non-conformances from the business perspective, such as related to cost, which is beyond the scope of the methodology. However,

evaluator F perceived the method from the *"technical aspect and the NoCoS matrix is applicable to engineers"*, whereas evaluator B described it as Critical to Quality (CTQ).

6.3.1.6 Overall evaluation

As shown in Table 6-9, all six evaluators agreed that overall the new approaches in product validation process were a coherent and practical method, and recommended in pre-production. Only evaluator A responded 'no' on practicality.

Table 6-9 Results of Phase 1 evaluation - overall

Q C7. In your opinion, after reviewing the new approaches to validation process, do you suggest that this proposition is

	Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i	coherent?	Yes	Yes	Yes	Yes	Yes	Yes
ii	practical?	No	Yes	Yes	Yes	Yes	Yes
iii	recommended?	Yes	Yes	Yes	Yes	Yes	Yes

3 items/18 responses (17 = Yes, 1 = No)

Evaluator A is sceptical of the practicality of the new approaches, especially the NoCoS methodology, which have not been implemented and tested in an actual pre-production setting. However, she understands that it is somewhat difficult to implement and test new ideas in sensitive and critical areas in well established companies. Overall, she perceived the new approaches as relevant and recommended for pre-production.

Evaluators agreed that this is a coherent procedure in identifying non-conformances resulting from mistakes. Evaluator B admitted that mistakes are a major source of non-conformances and this statement is supported by evaluator A, who said about 70% had a mistake-origin. Evaluator C now had a 'positive' perception on non-conformances rather than 'hating' them, and suggests to his subordinates to look into them seriously. Evaluator D recommends the new approaches be used beyond pre-production, which is the design stage.

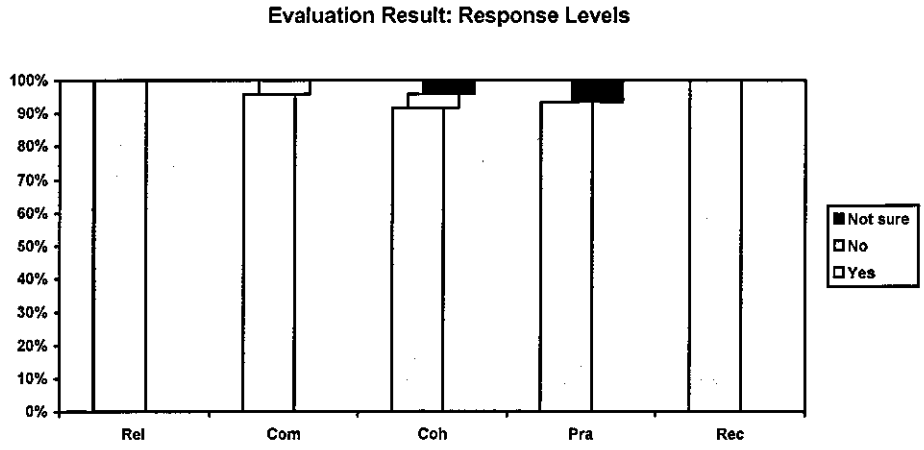
In addition, evaluator F provides a constructive suggestion. He suggests the new approaches and validation process should accommodate future changes, which means the procedure should be dynamic and continuously enhanced. This has been addressed in the NoCoS methodology, which considers unknown solutions as new non-conformances and hence accommodates future circumstances. Overall, evaluators considered the NoCoS methodology as providing a sensible approach in controlling non-conformances in pre-production.

6.3.1.7 Summary of closed-ended evaluation results

As mentioned in Section 6.2.7, the closed-ended questions in Phase 1 seek to identify the conceptual evaluation responses, as shown in Figure 6-2, in terms of relevance (Rel), comprehensiveness (Com), coherence (Coh), practicality (Pra), and recommended (Rec). Figure 6-2(a) presents the responses, in bar chart, with the following connotations: dots = 'Yes', diagonal lines = 'No', and black box = 'Not sure'. Figure 6-2(b) presents the total number and percentiles of responses on individual types of response.

On the optimistic side, evaluators assessed the new approaches as 100% relevant (30/30) and fully recommended (5/5) to be adopted in product validation in pre-production. An average 93.61% responded 'Yes' on (1) comprehensiveness (23/24 or 95.83%), (2) coherence (22/24 or 91.66%), and (3) practicality (28/30 or 93.33%). The results represent a significant evidence of the new approaches being practical and acceptable to industry.

The low pessimistic perception, answering 'No' (2 out of 48, or 4.17% responses) and 'Not sure' (3 out of 54, or 5.56% responses), is due to the new approaches not being implemented and tested, and issues of lack of deployment details. Since the evaluation is on the conceptual level not deployment, it is therefore appropriate to test, and the deployment details are presented in product validation through a validation process workbook, as described in Chapter 5.



(a)

Response type	*Total responses*	*Numbers & percentages of responses*			
		Yes	*No*	*Not sure*	*Don't know*
Rel = Relevant	30	30 (100%)	-	-	-
Com = Comprehensive	24	23 (95.83)	1 (4.17%)	-	-
Coh = Coherent	24	22 (91.66)	1 (4.17%)	1 (4.17%)	-
Pra = Practical	30	28 (93.33)	-	2 (6.67)	-
Rec = Recommended	5	5 (100%)	-	-	-

(b)

Figure 6-2 Evaluation results of closed-ended questions

Next is the Phase 2 evaluation on the acceptability of the PNC and NoCoS methodology when deployed into the product validation process. Evaluation is carried out by a validation team of three evaluators from different functions in the same company, each of which conducts validation from various aspects.

6.3.2 Phase 2 Evaluation Results

Three evaluators, designated X, Y and Z, participated in the evaluation, representing three departments in company D which carry out product validation in pre-production, are

- X represents Design Department (also the same evaluator as in Phase 1 evaluation)
- Y represents Production/Engineering Department
- Z represents Quality Assurance Department

Evaluator X was also answerable to all queries from the validation team regarding the product under validation.

Interviews were conducted with the three evaluators with open-ended questions based on a validation workbook (see Appendix B). The evaluation focuses on the new approaches, validation process, and validation workbook. The following section presents the results of evaluation on evaluators' perception, comments, criticism and suggestions. Transcription of the evaluators' responses is given in Appendix D2.

6.3.2.1 New approaches evaluation

Table 6-10 presents the responses on three questions related to the new approaches in the product validation process. Evaluators' perceptions on appropriateness of the new approaches have been regarded as relevant to the product validation process.

Table 6.10 Results of Phase 2 evaluation on new approaches

PART B Appropriateness of new approaches in pre-production			
Evaluator	*X*	*Y*	*Z*
1. Do you think identification of non-conformances based on product characteristics described in Section 3.1 is appropriate in product validation?	Essential	Appropriate	*
2. Do you think the manifestation of non-conformances based on the PNC, as described in Section 3.3, is valid?	Accurate	Valid	Valid
3. Do you think the NoCoS methodology, as described in Section 3.4, is appropriate in controlling non-conformances?	Complicated	Appropriate	Feasible

Note: * = inaccurate response

On item 1, evaluators' perception on identification of non-conformances was based on three product characteristics as described earlier, as *"essential and appropriate"* during

validation. Evaluator X admitted the company *"has not focused on identifying non-conformances"*. Evaluator Y insisted that the design department should identify non-conformances, not pre-production, yet agreed that pre-production *"may prevent the non-conformances escaping into the production"*. However, evaluator Z suggested priority should be given to *"problems commonly found in the market"*. It should be noted that non-conformances described in the new approaches are also related to problems commonly found in the market, for example, safety, aesthetics and functionality.

On item 2, the manifestation of non-conformances based on the PNC described in the workbook was found to be *"accurate and valid"* from the evaluators' experience. Evaluator X expected that non-conformances must have been found, claiming that the product is still under development, and admitted the effect on validation. Evaluators Y and Z suggested the list in Table 2-3 in the workbook be arranged in order of importance, for example '*work instruction and safety*' in Information Non-conformances should come first. The particulars listed in the table are not in order of importance, as it represents and describes the common items, where precedence is not applicable at this stage.

In commenting on item 3, the NoCoS methodology, evaluators' perception varied. Evaluator X claimed that the methodology is complicated as compared to the company's practice which uses the Simple Severity Ranking (as described in Chapter 5). Evaluator Y agreed that the NoCoS is appropriate, and evaluator Z perceived it as feasible, yet at the same time did not give any opinion as he has his *"own way of analysis"*.

6.3.2.2 Validation process evaluation

Table 6-11 presents the summary of results on five questions related to specific aspects of the validation process, with item 4 regarding the step-by-step procedure. Evaluators' perception with regard to practicability of the product validation process based on the new approaches was very positive, but with some criticism.

Table 6.11 Results of Phase 2 evaluation on product validation process

PART C Practicability of product validation process			
Evaluator	*X*	*Y*	*Z*
1. Do you think the product validation model, as described in Section 1.5, is appropriate in pre-production?	Appropriate	Appropriate	Appropriate
2. Do you think the **validation process steps,** *as described in Section 1.6, are appropriate in* pre-production?	*Logical*	*Incomplete*	*Appropriate*
3. Do you think that the **general rules,** as described in Section 3.1, are appropriate in product validation?	Good	Valid	Valid
4. Do you think the particular **steps** below are appropriate?			
Step 1 - INITIATION, as described in Section 3.2	Appropriate	Appropriate	Appropriate
Step 2 - DETECTION, as described in Section 3.3	Appropriate	Appropriate	Appropriate
Step 3 - ANALYSIS, as described in Section 3.4	Appropriate	Appropriate	*
Step 4 - RECTIFICATION, as described in Section 3.5	Incomplete	Incomplete	Incomplete
Step 5 - VERIFICATION, as described in Section 3.6	Appropriate	Appropriate	Appropriate
5. **Overall,** what do you think of the procedure?	Limited	*	*

Note: * = inaccurate response

On item 1, evaluators agreed the product validation model is *appropriate,* as it involves the key aspects which are design, production and pre-production. It reflects company current practice. The validation steps in item 2 were seen as logical and appropriate. Evaluator X agreed on having a separate checklist, one for identifying non-conformances rather than "*a general one*" since some problems are not described in a standard checklist. Evaluator Y commented that one of the steps (Step 2 – Detection) is incomplete, and suggests that an additional step in inspection of product (on reassembly) should be included. It is intentional that the procedure has excluded some additional details, specifically the operational aspect, in inspection tasks to provide generalisation to the validation process.

In item 3, a general rule has been prescribed for the effectiveness of the improved validation process. This includes 100% inspection also being exercised by evaluators Y and Z. Ironically, evaluator X (from design department) did not

conduct 100% inspection, other than on a case-by-case basis, the reason being *"takes more manpower and longer period"*.

On item 4, in evaluating individual steps of the validation procedure, evaluators generally agreed that Steps 1, 2, 3 and 5 are appropriate. For Step 4, evaluators criticised the lack of testing the solution to non-conformances before deployment, and the step is thus incomplete. Test can be carried out either during trial-run or re-validation, as described in the workbook, or before Step 5 – Verification.

On item 5, evaluator X commented that preventing new problems is not described in the procedure. It is the task of the design department to formulate the solutions to new problems; however, the procedure suggests mistake-proofing techniques as a practical prevention approach. Evaluators Y and Z did not respond accurately, but evaluator X perceived the validation process described in the validation workbook as relevant, appropriate, and having *"very good coverage and quite detailed"*.

6.3.2.3 Workbook evaluation

Table 6-12 presents a summary of results on three questions related to presentation of the validation workbook. Evaluators' perceptions on appropriateness of the validation workbook as a guide in the deployment of the new approaches have been generally acceptable and recommended.

Table 6.12 Results of Phase 2 evaluation on workbook

PART D Appropriateness of validation workbook			
Evaluator	*X*	*Y*	*Z*
1. What is your opinion on the **format or presentation?**	Reserved	Acceptable	Acceptable
2. Do you think the **annexes** and **examples** given in pages 46 to 58 are appropriate?	**	Relevant	Appropriate
3. What is your opinion on the overall workbook content?	Recommended	Recommended	Recommended

Note: ** = no response

On the format or presentation of the workbook (item 1), evaluators claim that it is *"acceptable"*, which is *"easy to follow and understand even by those not well versed in*

English". With regard to supplementary information, which are annexes and examples (item 2), they are relevant and acceptable. However, evaluator X is *"not sure of its implementable"*, and suggests further elaboration. As a general guide, the workbook is intended to provide key procedures but companies can customise the format and presentation according to company standards. Yet the evaluator agrees the workbook *"is very clear, the procedure can be followed quite easily, the layout is simple, and straight to the point"*.

One suggestion proposed for better understanding of the procedure is to *"provide an example of actual walkthrough step-by-step deployment"* besides the three sections (purpose, procedure and activity) described in each step in the workbook. This is felt to be a good idea but it will be more appropriate if an example of deployment is adopted and explained in the context of companies wishing to use and customise the workbook.

On the final item, overall the workbook is relevant in product validation, comprehensive in coverage, and presented in a coherent manner. It is very practical as *"a background understanding and reference"* on the product validation process, and relevant as training material for new staff. The next section summarises key evaluation outcome in terms of benefits, limitations, and suggestions from the new approaches.

6.3.3 Benefits of New Approaches

The main benefit of the new approaches is the establishment of the non-conformances classification, based on product characteristics, as the consequence of mistakes. Evaluators confirmed the three key product characteristics represent the components of the product under validation. This leads to '*categorically correct in defining non-conformances*', simple to understand, and generally covering major consequences and solutions. This allows a better understanding of product non-conformance, and subsequently improved identification and control of non-conformances during product validation.

The comprehensive validation process, enhanced with the new approaches, and presented in a validation workbook provides good information and initial learning regarding the procedure and conduct of the validation process in pre-production. It

facilitates training purposes for new, junior, and staff who have limited experience and access to appropriate assistance. Other benefits of the new approaches identified from evaluation include:

- They provide an innovative way for avoiding and/or reducing the consequences of non-conformances during and after pre-production.
- They provide companies with a well defined and systematic approach to identifying the characteristics of product non-conformance which are types, manifestation of mistakes, and processes, measurements and techniques of determining their consequences, solution and prevention.
- They provide a structured and workable approach to documenting and presenting the non-conformances.
- They provide guidance on the product validation process in pre-production.
- They can be used by design, validation, and production teams as product assessment methodology and are scalable for any development and production of consumer electronic products.

6.3.4 Limitations of New Approaches

Limitation of the new approaches was made regarding operational details which were beyond the validation procedure, for example testing of the non-conformance solutions before deployment and examples. As stated in the NoCoS methodology, the solutions consist of four kinds of maturity status. These are solutions which have been tested, and result in various conditions. Hence, for rapid rectification, known and introduced (tested 'o.k.') solutions should be deployed.

6.3.5 Enhancement of New approaches

The effectiveness of the validation process workbook can be further enhanced with more examples. These are practically good suggestions which can be implemented according to the individual company's operational requirements. Moreover, the new approaches require continuous enhancement to cater for manifestation of new non-conformances and mistakes which are unique from one company to another.

Suggestions were also made to cater for training of validation teams, operators, and suppliers as well, on the concepts and deployment of the new approaches.

The next section concludes the evaluation chapter with discussion on evaluation results and suitability of the evaluation approach.

6.4 DISCUSSION

The new approaches in identification and control of non-conformances have been evaluated in two phases. In the evaluation, a new non-conformance classification - Product-based Non-conformances Classification (PNC); and the control method - Non-conformances Consequence-Solution (NoCoS) methodology, have been assessed. The evaluation is to establish the potential of new approaches in the validation process. The following sections summarise the Phases 1 and 2 evaluations, and discuss the suitability of the evaluation approach.

6.4.1 Summary of Evaluation Results

Overall, evaluators' perceptions are significantly favourable on practicability and acceptability of the new approaches (see Section 6.3.1.7), although there are limitations and some suggestions for improvements, as summarised in Table 6-13. Subsequently, from the evaluation,

1. the relevance and comprehensiveness of the new approaches in addressing product non-conformance has been confirmed with a high level of positive comments,
2. evaluators were satisfied that the approaches are coherence and capability of identifying and controlling non-conformances during validation,
3. in assessing the feasibility with which it can be deployed, some evaluators agreed that detailed elaboration and operational particulars are needed,
4. for appropriate deployment of the approaches in pre-production, training is suggested to facilitate understanding and to familiarise with the concepts and their deployment.

Table 6-13 Summary of evaluation responses

	Benefits	*Limitations*	*Suggestions*
PNC	Categorically defines non-conformances	Operational details not included.	Training
NoCoS			
Validation Process Workbook	As background understanding and reference		Further elaboration with example of deployment

6.4.2 Suitability of Evaluation Approaches

The interview sessions and evaluation process have been conducted successfully, with full cooperation from evaluators representing various multinational companies. Evaluation objectives have been met as evidenced from positive responses from evaluators, judging from various pre-production practices. Yet, as described in Section 6.2.6, the interview has strength, weaknesses and limitation, and in addition the conduct of evaluation has the following results:

- *Schedule of questions*: The questions were designed based on the aspects of evaluation, using both closed and open-ended questions, and supported with illustrations of the new approaches. The open/closed-ended questions gave ample opportunity for both evaluators and interviewer to clarify ambiguity, and sharing and probing in-depth information thus provided accurate and useful responses. However, due to time constraint in the evaluation sessions, the questions have been limited and restricted, as described in Section 6.2.7.

- *Concept evaluation*: Evaluators were selected based on their capacity, role and experience in product development, pre-production and product validation. They understand better on a practical scope the principles, concepts and deployment, and the subject being addressed. Hence, they are highly eligible to provide relevant, appropriate and accurate responses regarding conceptual aspects of the new approaches. Although the illustrative and comprehensive questionnaires about the concepts (see Appendix C1) were issued to evaluators prior to interview, they still required explanation and clarification on some aspects of the

CHAPTER 7

DISCUSSION, CONCLUSIONS AND FURTHER WORK

7.1 INTRODUCTION

The research was aimed at exploring and investigating product non-conformance and validation practices to provide improved identification and control of non-conformances in pre-production. This aim has been achieved through five research objectives, as outlined in Chapter 1, realised throughout the chapters of the thesis, as follows:

1. The literature and industrial investigation have provided comprehensive understanding of the source of non-conformances and their link with the product under validation, and have identified the elements for improved validation practices, as elaborated in Chapters 2 and 3.
2. Critical aspects of the identification of non-conformances have been defined and a control methodology has been determined.
3. From these, the concepts of the new approaches in addressing non-conformances have been formulated, as described in Chapter 4.
4. A product validation workbook has been generated based on the new approaches which outlined the deployment of the improved product validation to aid the identification and control of non-conformances, as described in Chapter 5.
5. Expert evaluation has been carried out to validate and verify the applicability of the concepts and deployment of the new approaches, as described in Chapter 6.

This chapter completes the research and thesis report by presenting a discussion on the major aspects related to the research objectives in Section 7.2, research contributions in Section 7.3, a list of conclusions in Section 7.4 and recommendations for further work in Section 7.5.

7.2 DISCUSSION

This research has addressed product non-conformance in pre-production and has adopted a holistic approach which is believed to be essential in order to provide a comprehensive and rapid rectification to non-conformances. The discussion of the approach is concerned with interrelated aspects of non-conformances through the manifestation of mistakes, non-conformance classification, and non-conformance consequences and solutions, as shown in Figure 7-1, and the deployment and evaluation of the approach, and followed by reviewing the research method.

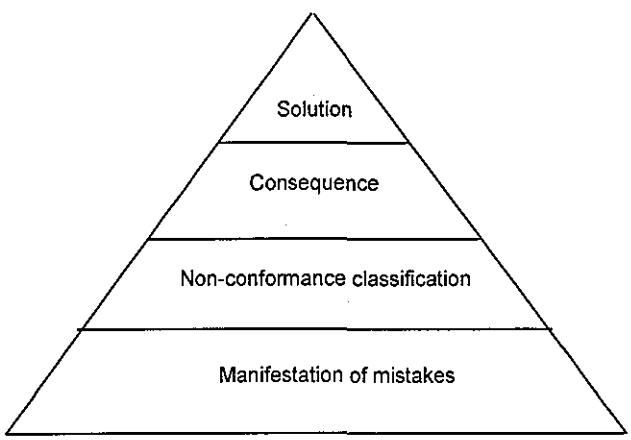


Figure 7-1 Holistic approach in addressing product non-conformance

7.2.1 Development, Deployment and Evaluation of New Approach

In this research, the works by Shingo (1986) and Hinckley (2001) related to mistakes have been adapted and extended in addressing product non-conformance and validation. While their work focuses on manifestation of mistakes related to production, this research focuses on analysing mistakes in the product under validation in pre-production in order to avoid them from appearing in production. It has been shown that analysis of mistakes can substantially improve the product validation process. Mistakes have been grouped according to a new classification of non-conformances to aid identification and control of non-conformances during validation. In pre-production, addressing mistakes is important because they are the major source of non-conformances, furthermore they are tangible, not time-dependent, and can be resolved immediately as they appear.

Although the work in this thesis focuses on mistakes, it has been shown that there are other sources of non-conformance linked with mistakes which are complexity and variation (Hinckley, 2001), as described in Chapter 2. It is logical that product complexity and variation should have been resolved earlier before pre-production; however, the potential for mistakes to appear is high if complexities are not reduced and variation is not controlled in the design of product. A useful extension to this work would therefore be to address complexity and variation and their links to mistakes and consequently to non-conformances in pre-production.

This research does not suggest ways to put an end to or solve product non-conformances completely, but presents ways to reduce and prevent non-conformances from escaping beyond pre-production. This differs from existing work which focuses on (i) the implications of non-conformances which are predominantly in terms of cost (Crosby, 1979; Feigenbaum, 1991; Juran and Godfrey, 1999), and (ii) problem-analysis on specific manifestations of non-conformances (de Castro and Fernandes, 2004; Das, 2004; Dillon, 2005; Murthy and Blischke, 2006). Although the work in this thesis focuses on product non-conformance related to mistakes and product characteristics, there are other aspects of non-conformances that could be explored, particularly on product performance and reliability, which were excluded from this research due to their complexity and extent of the issue. Extended study from this research is needed through longitudinal empirical research in order to address these aspects of non-conformance. Only then can non-conformances be comprehended completely.

In this research, the work by Yuan (2002) related to assessing product quality has been adapted and extended in addressing product non-conformance in pre-production. It has been shown that the methodology introduced in this thesis enables rapid assessment and facilitates the improved validation process, as described in Chapter 6, and is capable of providing consistency in assessment and preventing varying interpretations of non-conformances among validation teams. This method can be further expanded to incorporate the SSR approach which is commonly adopted in industry. At implementation or company level, the severity of each consequence further classified into critical, major and minor, as seen appropriate, is to be included in the relationship matrix. Industrial case study is needed to explore how various companies may be

similar or different in assessing and defining non-conformances when the NoCoS methodology is adopted together with the SSR approach.

Similarly, the product validation workbook has been perceived to be adequate and recommended in deploying the improved product validation, as described in the Phase 2 evaluation of Chapter 6, Section 6.3.2. It has been shown that the workbook can be used to support the people involved in conducting validation in pre-production, as described in Chapter 6, Section 6.3.2.3. However, there is a need to implement and test the approaches and use the workbook in the actual product validation process in order to evaluate the strengths and weaknesses. There is also a need to explore other additional material to support the workbook, such as (i) the use of software to log, analyse, report, store and disseminate information on non-conformances, (ii) a booklet and/or software containing historical cases of non-conformances according to mistakes, classes, consequences and solutions; and (iii) explanatory and training materials.

7.2.2 Reviewing Research Methodology

The study has adopted a qualitative research, analysing a contemporary phenomenon through direct observation and experience, in an actual setting to understand and interpret the phenomenon under study, which is product non-conformance. Product non-conformance, in any design and manufacturing industry, is a universal issue in product development and pre-production, as described in Chapter 2. The thesis illustrates the issue by presenting data or evidence on product non-conformance of consumer electronic product obtained from a multinational company where the researcher has worked.

Due to sensitivity (relating also to reputation), the company's actual or data of non-conformances were not presented. However, it gave permission for data to be presented descriptively or illustrated by secondary means, as in Chapter 3, Section 3.4. The risk of presenting through secondary means is that there may be a tendency of 'bias and convenience' in the selection of the data to suit a research, for example, choosing unrelated or non-genuine data from other sources. To avoid these circumstances, the secondary means presented in this thesis have been carefully replicated based on data permitted by the company. This approach is argued to be an equally valid method.

According to Amaratunga et al. (2002) (cited in Mohamed, 2006) *the emphasis should be on understanding the phenomena as they occur in their context, not method.* In order for a research to present actual data or sources, a study is needed on various companies from the consumer electronic products industry, focusing on one or two cases of non-conformances; then to compile, analyse and report collectively. A few cases of non-conformances from each company will not risk individual company reputation.

The implementation and testing of the new approaches in a real pre-production setting in the consumer electronic product industry have not been undertaken. Companies are reluctant to permit this activity due to the confidentiality of their pre-production facility. This condition is not uncommon in well established and major players in the consumer electronic product industry. Therefore, the validation of the methodology is through experts' opinion to evaluate its potential and feasibility for the industry. Two evaluation stages were conducted. The conceptual framework was evaluated by experts from various companies who have extensive experience and hold key positions in product development and pre-production. The operational aspects were assessed by experts representing different functions in a company and involved hands-on in the day-to-day validation of products. They assessed the deployment of the methodology through the product validation workbook. Hence, after establishing and confirming the potential of the new methodology conceptually and operationally, immediate work could proceed to persuade companies, either a small or major player in the industry, to implement and test the methods in actual pre-production.

The scope of this research has been limited in addressing non-conformances within consumer electronic product. The new approaches have been evaluated to be feasible by experts from a range of manufacturers. Thus the concepts and the improved product validation process are only applicable within this category of product. The application cannot be generalised to other types of consumer products, such as automobiles, unless the broader classification and control of non-conformance have been deployed and tested. A study needs to be initiated, continuing from this research, to provide wider application of the new approaches.

7.3 RESEARCH CONTRIBUTIONS

1. This research provides a significant contribution with the introduction of a new classification of non-conformances which improved the conduct of product validation in pre-production. The classification is known as Product-based Non-conformance Classification (PNC) which is based on mistakes manifested in tangible characteristics of the product under validation. It has been shown that it is possible to formulate a comprehensive understanding of non-conformances by linking mistakes and product characteristics. Understanding this relationship aids in control and prevents non-conformances from leaving pre-production.

2. A rapid method of assessing product non-conformance during validation, called Non-conformance Consequences and Solution (NoCoS) has been introduced. This method enabled non-conformances to be explicitly described based on a critical consequences and solutions condition of identified non-conformances, unlike existing approaches such as FMEA and SSR, which have not included solutions. The contribution of this method includes (i) simple way of quantifying non-conformances by means of a relationship matrix, and (ii) incorporating solution condition of non-conformances in the assessment.

3. A novel outcome of this research is a product validation workbook which has been formulated based on the new non-conformance classification (PNC) and control methodology (NoCoS), as given in Appendix B. The workbook is a guide to conduct the improved product validation. From the experts' evaluation, the concepts which are deployed in the workbook have been perceived to be practical in addressing product non-conformance in pre-production,

7.4 CONCLUSIONS

The motivation of this research has been to explore effective and efficient ways to identify and prevent non-conformances as much as possible during the pre-production stage. This research has described and demonstrated that this initiative has been

achieved with the introduction of new non-conformance classification and rapid control methodology. The conclusions drawn from this research are as follows:

- It has been shown that the new non-conformance classification and control method introduced has addressed non-conformances and facilitated improved product validation process in pre-production, as described in Chapter 6. The classification of non-conformance have been defined based on the characteristics of the product under validation and mistakes, and the control method have been defined based on non-conformance consequences and solution conditions, as explained in Chapters 4 and 5.

- It has been established that the product under validation is composed of three generic characteristics: information, process and parts/components, as described in Chapters 3 and 4. These have provided a practical foundation in the formulation of new classification of non-conformances. The classification represents three groups of non-conformances related to the particular product characteristic, which enabled comprehensive, consistent and rapid identification of non-conformances, as described in Chapter 6.

- It has been shown that the method of controlling non-conformances has facilitated the improved product validation process which enables analysis, priority, rectifying and reporting of non-conformances. The method provides the link between the sources, the occurrences, the consequences, and the solutions of non-conformances, presented in the form of a relationship matrix, as described in Chapters 4 and 5.

- The relationship matrix in the control method presents the identified non-conformances in relation to their consequences and solutions. It has been shown that this matrix facilitates analysis and quantification which is important to measure the non-conformances of product under validation and for further scrutiny.

- It has been shown that existing methods of addressing non-conformances focuses on analysis and priority without incorporating solutions. Adopting a holistic approach, which includes identifying the manifestation of mistakes, analysing non-conformances, and determining the consequences and the solutions, has shown to be a pragmatic approach in addressing non-conformances in pre-production.

- It has been shown that non-conformance criteria can be integrated with conformance criteria into an inspection checklist in order to facilitate effective validation. Checking for common and potential non-conformances along with conformances can avoid over sighting both critical and minute validation consideration, as described in Chapter 5 Section 5.3.4.2, subsequently enabling prevention of non-conformances from leaving pre-production.

- A structured written guideline for the improved product validation has been provided in the form of a workbook. As described in Chapter 6, experts evaluation has been carried out which verified the feasibility of the new approaches in terms of (i) establishing the manifestation of various type of mistakes (ii) associating mistakes with the classes of non-conformances, (iii) relating non-conformances with critical consequences, (iv) determining non-conformances with appropriate solution conditions, and (v) suggesting and confirming the practicality of the approaches.

7.5 FURTHER WORK

Besides further work suggested earlier in the discussion section, there is scope for research which extends the study reported in this thesis. Further recommended research and development work includes the following:

- It has been shown that the multinational company on which the research is based, the actual evidence of non-conformances identified in pre-production are sensitive to be presented, while testing of the new approaches in a real setting

has been an impediment. In order to present an empirical research, there is a need for an action research initiated by a company prepared for this type of research problem. The study should focus on new product not yet marketed, or/and reuse historical data on non-conformances of obsolete products. With the new approaches introduced in this thesis, companies can be persuaded for the study, to implement and test the approaches in their pre-production. With company-initiated research, data on product non-conformances are more accessible, and testing the new approaches is possible with wider participation within the company, hence the report can be disseminated to the public domain.

- The expert evaluations have been conducted on the conceptual level of the new approaches and deployed through a validation workbook. In order to enhance the new approaches further, there is a need to implement and test at operational level in the actual company pre-production setting. Further research based on action research in needed on the implementation and testing of the strengths and weakness of the new approaches, for example ease of use, validation time, consistency, accuracy, etc.

- The evaluation of the new approaches has been done by experts from six companies which have been seen as adequate to generalise their potential and feasibility. There is however a need to demonstrate in a broader perspective their practicality and acceptability in addressing product non-conformance. Hence, the new approaches need to be implemented and tested in diverse consumer electronic products, in various validation practices scenarios, and in a wider range of companies.

- A direct implication of the new approaches has been the acceptability of and confidence in the concepts and deployment by industry, as demonstrated from the evaluation in Chapter 6. However, investigation on other implications of the new approaches needs to be explored such as (i) for business, in terms of assessing and measuring non-conformances in relation to *Cost of Poor Quality (COPQ)*, as described in Chapter 2, Section 2.2.3; and (ii) for design, in terms of facilitating the development of products and processes in order to achieve full

conformance, and minimising and preventing non-conformances, as depicted in Chapter 2, Figure 2-3.

- It has been shown that in addressing non-conformances, there are variations in interpretation and perception among people involved in validation at this critical stage of product development. In order to provide consistent and accurate interpretation and perception, there is a need for an information system based on the new approaches. Therefore, this calls for people with experience, knowledge, and involved in addressing product non-conformance and other quality-related issues, able to store, share, update and disseminate their expertise and know-how. Subsequently, aids in delivering comprehensive and rapid solutions and prevention of non-conformances during pre-production.

- In order to benefit the advantages provided by the new approaches, a study is needed to (i) demonstrate their potential if adopted with other evaluation practices in other functions such as design, production, marketing, maintenance, engineering, etc., (ii) explore the compatibility of the new approaches in the validation of other types of products such as automobile, tools/equipment, machinery, electronics, etc., and (iii) explore the compatibility of the new approaches in different companies having different priorities, strategies and considerations in pre-production. These investigations may be conducted through a wider research approach such as simulations, comparative studies and surveys.

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APPENDIX A: Engineering COQ elements (source: Johnson, 1995)

1. Price of Conformance (POC): Prevention Costs Elements

Design specification reviews
Service design qualification
Design support activities
Design feasibility studies
Preparation of design manuals and procedures
Design and development of quality measurement and control equipment
Product qualification
Personnel qualification
Packaging qualification
Vendor surveillance and rating/qualification
Drawing checks
Supplier evaluation
Preventive maintenance
Verify workmanship standards
Review of test specifications
Failure effects mode analysis
Pilot production runs
Customer interface
Safety review/operator safety
Technical manuals
Pre-production reviews
Defect prevention programme
Schedule reviews
Process reviews
First piece approval
Agency approval
Prototype inspection and test
Receiving sample testing
In-process sample testing
Final sample testing
Laboratory analysis and test
Fault insertion test
Engineering audits
Training for special testing
Customer/user perception surveys/clinics
Contract/document review
Field trials
Purchase order technical data reviews
Supplier quality planning
Maintaining engineering files
Process capability studies
Hazard/operability studies
Economic analysis/studies
Building code studies/reviews
Materials of construction studies
Process simulation studies
Checking of vendor prints
Shop inspections, vendor equipment, material
Off-site field/shop trials
Outside endorsements/certifications
Field checking of piping isometrics
Quality improvement activities
Engineering quality orientation
Supplier quality seminars
Quality orientation acceptance planning
Quality audits
Quality planning report
Data analysis and preventive action
Purchasing prevention costs
Quality administration
Quality performance reporting
Quality circles
Procedures preparation
Project review and meeting
Planned maintenance
Archiving of data
Conformance analysis
Process control
Packaging inspection
Status measurement
Inspection labour
Quality control labour
Test labour
Equipment costs
Consumer affairs
Quality programme development
Preparation of quality documentation
Quality data acquisition and analysis
Quality engineering
Maintenance and calibration of equipment
Re-inspection or retesting

(continued)

APPENDIX A (continued)

2. Price of Non-Conformance (PONC): *Appraisal Costs Elements*

Design quality progress reviews, evaluation and characterisation
Scrap/rework tracking/reporting
Vendor quality tracking
F/O tracking system audits
Appraisal/resolution
Production test
Department/function quality measurement tracking
Laboratory acceptance testing
Testing set-up of inspection and test
Personnel appraisal
Accumulation of cost data
Purchasing appraisal costs
Process control
Outside endorsements and certifications
Field performance evaluation
Prototype inspection and test
Post-project reviews
Production specification conformance analysis
Process control acceptance
Packaging inspection
Status measurement and reporting
Conformance analysis

Price of Non-Conformance (PONC): *Failure Costs Elements*

Design corrective action
General notes
Dimensions/tolerances
Revision block
Title block
Work crafting
External detailing
Lines/arrows
Subcontract/format
Sectional reviews
Documentation revisions owing to errors
Supplier-caused losses
Troubleshooting
Remedial engineering
Show down time
Purchased material reject disposition costs
Extra operations
Field service
Complaint investigations/customer or user service
Retrofit costs
Recall costs
Liability costs
Equipment breakdown/repairs
Work performed but not used
Equipment/materials purchased but not used
Unplanned (unnecessary) visitors
Engineering errors and omissions
Owner-operator changes
Vendor errors and omissions
Contractor changes
Remedial work associated with warranties and guarantees
Wasted man-hours resulting from late start of meetings
Costs from errors in scheduling
Engineering change order
Purchasing change order
Corrective action costs
Service after service
Consumer affairs
Software changes
Engineering and drafting time spent on re-design work
Material review activities
Time spent expediting purchase orders
Premium freight owing to late issue of drawings
Engineering time spent on failure analysis
Repair and redesign owing to incorrect materials specified
Wasted prefabrication owing to inaccurate design
Design changes after initial approval
Delays caused by incomplete engineering drawings
Engineering travel and time on problems
Premium freight costs
Rework
In process scrap
Delays and rerouting for rework
Installation repair work
Premature failure in early service
Warranty repair and replacement
Complaints
Failure reports
Return goods analysis
Design-related product liability
Explanation time
Lost production resulting from engineering schedule delays
Lost customer/user goodwill
Lost sales

APPENDIX B: PRODUCT VALIDATION WORKBOOK

Workbook for Product Validation

Identifying and Controlling Product Non-conformances in Pre-production

(v.3)

Roslan Jamaludin

WOLFSON SMME
LOUGHBOROUGH UNIVERSITY
Leicestershire, UK

December 2006

BACKGROUND

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DEFINTIONS

BACKGROUND

This workbook is a procedure for product validation. It describes the significance of identifying and controlling product non-conformances in pre-production, gives a general overview of the validation process, and explains the five steps of the validation process, derived from case studies, literature surveys and expert reviews.

The validation workbook is a set of procedures which are generic in structure and can be used to validate new or improved products in pre-production. Hence, the workbook attempts to set a standard that is practicable in manufacturing industry.

The validation procedure in this workbook gives special attention to two aspects:

- Non-conformances due to mistakes, since these are the most common cause.
- Inspection as the means of validation (testing is not in the scope of this validation procedure).

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2.5 Step 4 - RECTIFICATION

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DEFINITIONS

Non-conformances – Manifestation of product failure to meet design specification, quality and production requirements, and customer requirements.

Product-based Non-conformances Classification or PNC – Non-conformances are classified into three groups – Information, Process and Parts/Components, based on product characteristics. Non-conformances are manifested as the results of mistakes such as wrong part, omitted dimension, misadjustment, etc..

Non-conformance Consequences and Solutions or NoCoS – It describes five consequence levels and four solution statuses related to non-conformances.

NoCoS matrix – A relationship table in which identified non-conformances are logged and tabulated for further analysis.

Validation samples – Products produced by the design team in small volume for validation purposes.

Trial-run samples – Products produced by the production line in small volume for validation purposes.

Information – Official and standard documented references to a product, e.g. drawings, work instructions, checklists, standards, etc..

Process – In typical pre-production, the trial-run involves processes such as manual processes, automated processes, sub-assemblies, final assemblies, packaging, and handling.

Parts/Components – Loose or semi-assembled materials to assemble in final product, i.e. electrical, electronics, mechanical parts, accessories, packaging, etc..

Control items – In the validation model, the control items consist of three elements: the information, process and parts/components.

Consequence – In the NoCoS methodology, five levels of consequences are introduced based on undesirable effects of non-conformances towards product safety, producibility, and customer expectation.

Solution – Non-conformances which already have some kind of solution. Known solutions are determined in the NoCoS methodology as 'solution not yet positive', 'solution not yet introduced', and 'solution introduced'.

1. OVERVIEW

1. OVERVIEW

1.1 Introduction

Throughout development, a product undergoes a sequence of reviews. Reviews are a rigorous and formal means for assessing the product under development. As a result of the reviews, the level of a product conforming to specification and requirements increases, while the level of non-conforming reduces towards the completion of the development, as shown in Figure 1-1.

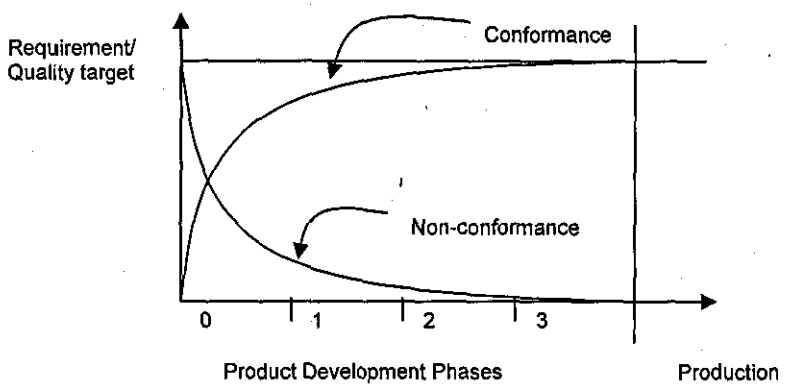


Figure 1-1 Expected review results from each stage of development.

Two basic characteristics should be reviewed in a product: reliability and quality. Failure to achieve the accepted level for these two characteristics will have costly consequences. Reliability has the influence of time before a consequence is manifested, quality does not. Flaw in quality is identified as the product materialises. Furthermore, non-conformances in quality are too often discovered very late, such as during full production and in the hands of customers.

The final review of development, i.e. before a product is released for full production, is the pre-production validation. The pre-production validation is done to ensure that product non-conformances do not escape into production. Therefore, it is vital to have an effective mechanism to identify, recover and prevent non-conformances earlier when recovery is inexpensive, rather than in later stages when it is very costly. Hence, the validation should emphasise checking for non-conformances.

This workbook takes users through a validation procedure focusing on non-conformances to ensure that they are identified and rectified during pre-production. The workbook consists of a formal validation process which aims at delivering quality and producible products that meet customer expectation.

1.2 Purpose

The objectives of this workbook are:

1. To explain the validation procedure and how to use it correctly.
2. To provide an approach to validation that emphasises identifying and controlling non-conformances.

The characteristics of the procedure are as follows:

- Systematic and easily understood.
- Simple in structure.
- Clear links between elements or steps outlined.

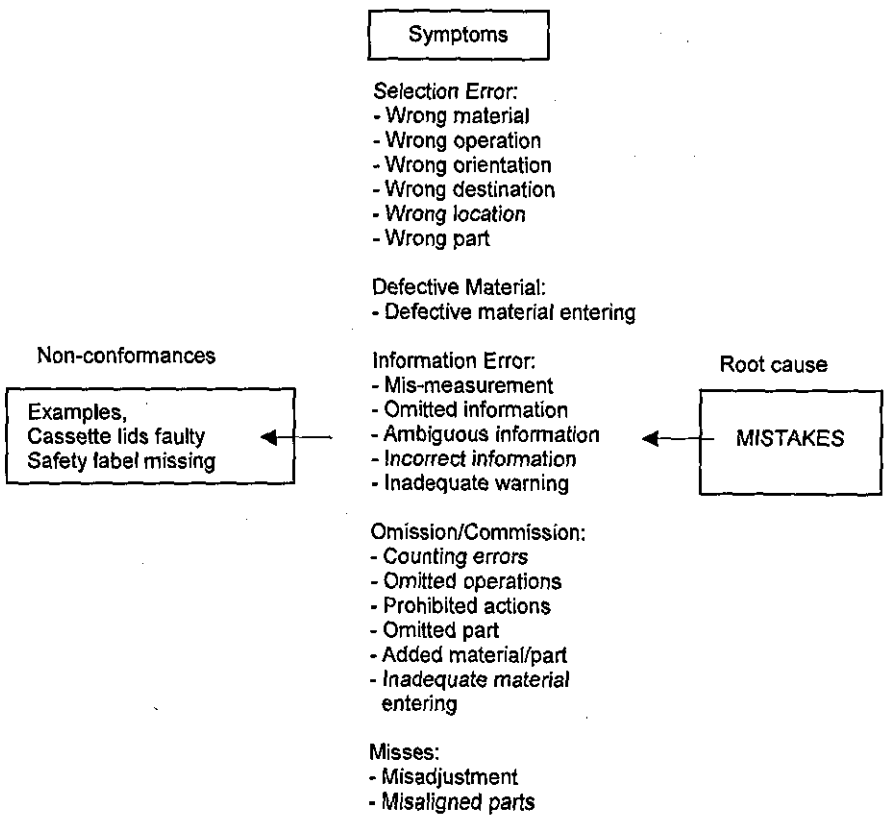
This workbook is divided into three sections. Section 1 provides an overview of the validation process. Section 2 defines the key terms used throughout the workbook. Section 3 describes the steps, purposes, procedures and activities. In addition to the three sections, this workbook also includes examples in the annexes.

1.3 Scope

This workbook describes the procedure to facilitate product validation in pre-production. The procedure outlines a validation process which can be used on many types of products. This procedure is deployed step-by-step through formal inspection, analysis and problem-solving activities. The scope ranges from preparation to verification.

The validation in this workbook gives special attention to two aspects:

- Non-conformances that are due to mistakes, as the major cause of non-conformances (see Figure 1-2). However, other causes contributing to non-conformances, i.e. complexity and variation [1] are not included.
- Inspection as the means of validation. Other validation mechanisms such as testing and simulation are not included.



Source: Hinckley (2001)

Figure 1-2 Non-conformances, symptoms and root cause.

1.4 Product Validation in Pre-production

In pre-production, the validation is conducted on two aspects, as depicted in Figure 1-3:

- Validation samples produced by Design team
- Trial-run assemblies by Production team
- Validation of samples and trial run by validation team

The Engineering Team is the moderator, and is responsible for conducting the validation with support from the Design and Production teams. The purpose of product validation is to identify and control non-conformances prior to full production.

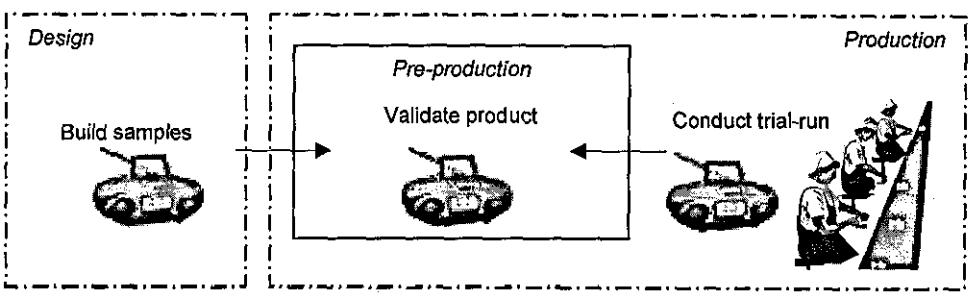


Figure 1-3 Product validation in pre-production.

1.5 Validation Model

"*A model is a representation of a set of components (elements) of a system or subject area. The model is developed for understanding, analysis, improvement or replacement of the system. Systems are composed of interfacing or interdependent parts that work together to perform a useful function. System parts can be any combination of things, including people, information, software, processes, equipment, products, or raw materials. The model describes what a system does, what controls it, what things it works on, what means it uses to perform its functions, and what it produces.*" [2].

The validation process consists of five basic elements, as shown in Figure 1-4:

1. Input, the objects to be transformed by the process into an output.
2. Output, the objects produced by the process.
3. Controls, the items required to produce correct output.
4. Mechanism, means used to perform the process.
5. Process, activities of transforming objects into what must be accomplished.

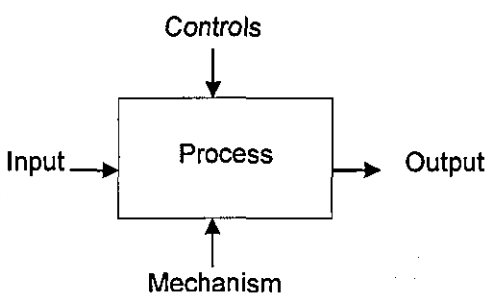


Figure 1-4 Validation process basic elements.

Derived from the figure above, a conceptual validation model is illustrated in Figure 1-5. The model consists of:

1. Input, corresponding to *Product under validation,* the validation and trial-run samples.
2. Output, corresponding to *Conforming Product* (product which fully conforms to specification), or *Non-conforming Product* (product which deviates from specification).

3. Controls, corresponding to product's *Information, Process and Parts/Components*, which are the consideration and references used to validate samples/product (see Figure 1-6).
4. Mechanism, corresponding to *Inspection,* the means to identify non-conformances.
5. Process, corresponding to *Validate Product,* i.e. the process of validation.

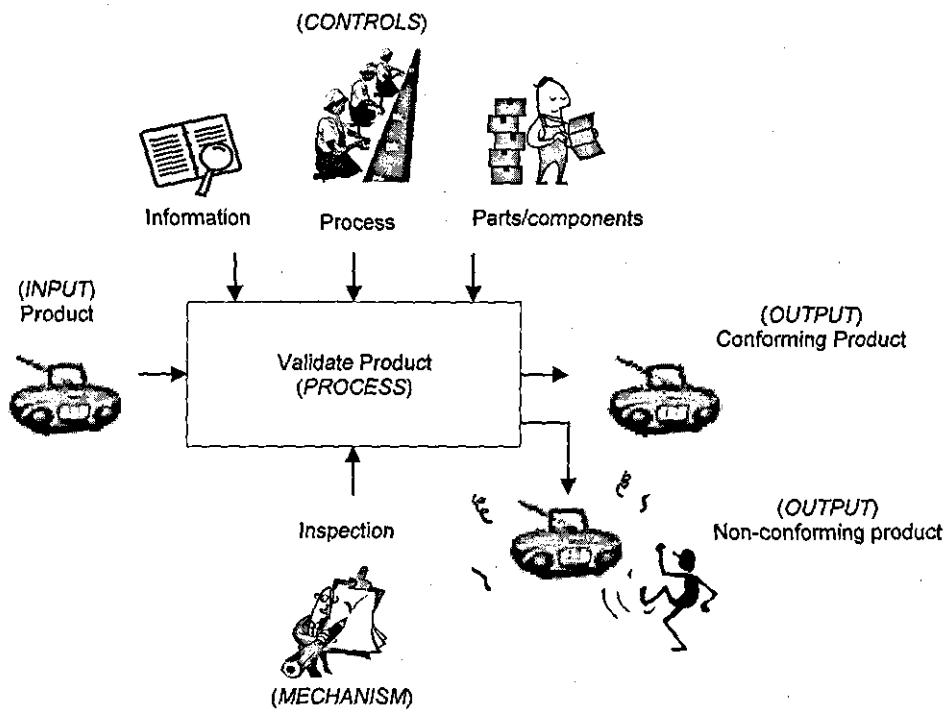


Figure 1-5 Product validation model

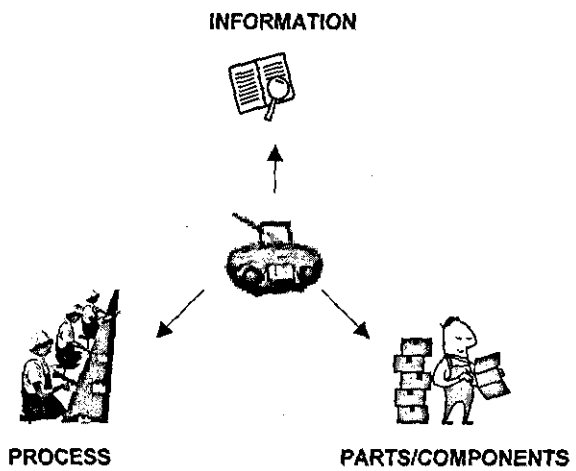


Figure 1-6 Three main validation considerations.

1.6 Validation Process Steps

A summary of the validation process is shown in Table 1-1:

Table 1-1 Summary of validation process steps.

Steps	Description	Objectives
1. Initiation	Obtaining and preparing all variables necessary before inspection.	Establish and prepare participants, product, resources, etc. Familiarise with inspection materials.
2. Detection	Formal inspecting of product and all relevant aspects of product.	Identify and record any abnormalities and non-conformances, by means of inspection.
3. Analysis	Assessing and defining non-conformances.	Define and classify non-conformances based on PNC and NoCoS methodology.
4. Rectification	Deploying solutions and prevention of non-conformances.	Deploy solutions based on NoCoS methodology and plan prevention of non-conformances.
5. Verification	Verifying inspection and rectification of all non-conformances.	Certify inspection and rectification completed satisfactorily.

The validation process consists of five steps, as shown in Figure 1-7. Details of each step are described in the following sections. Figure 1-8 illustrates the scenario in which non-conformances are to be identified and assess using the PNC and NoCoS methodology.

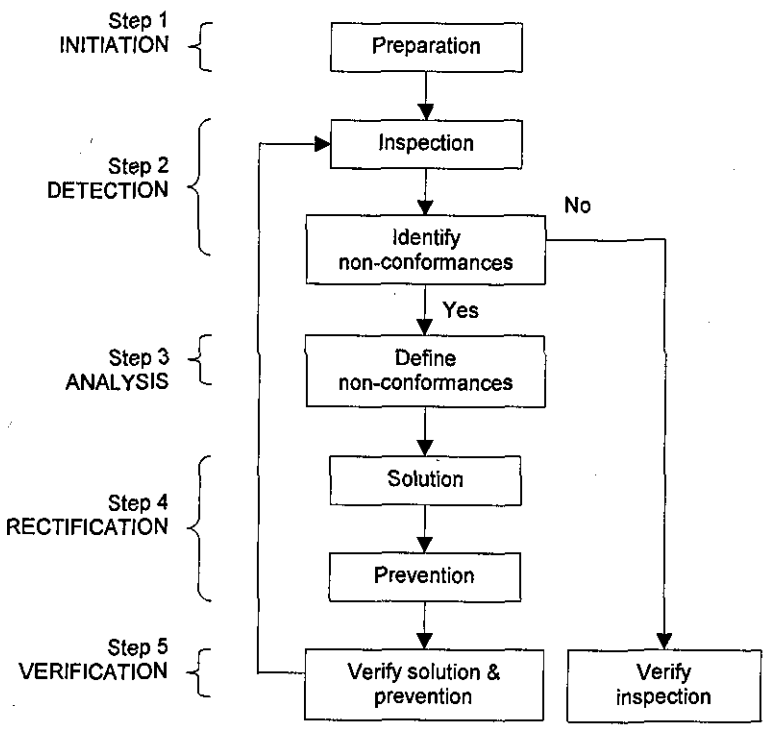


Figure 1-7 Validation process and activity flow diagram.

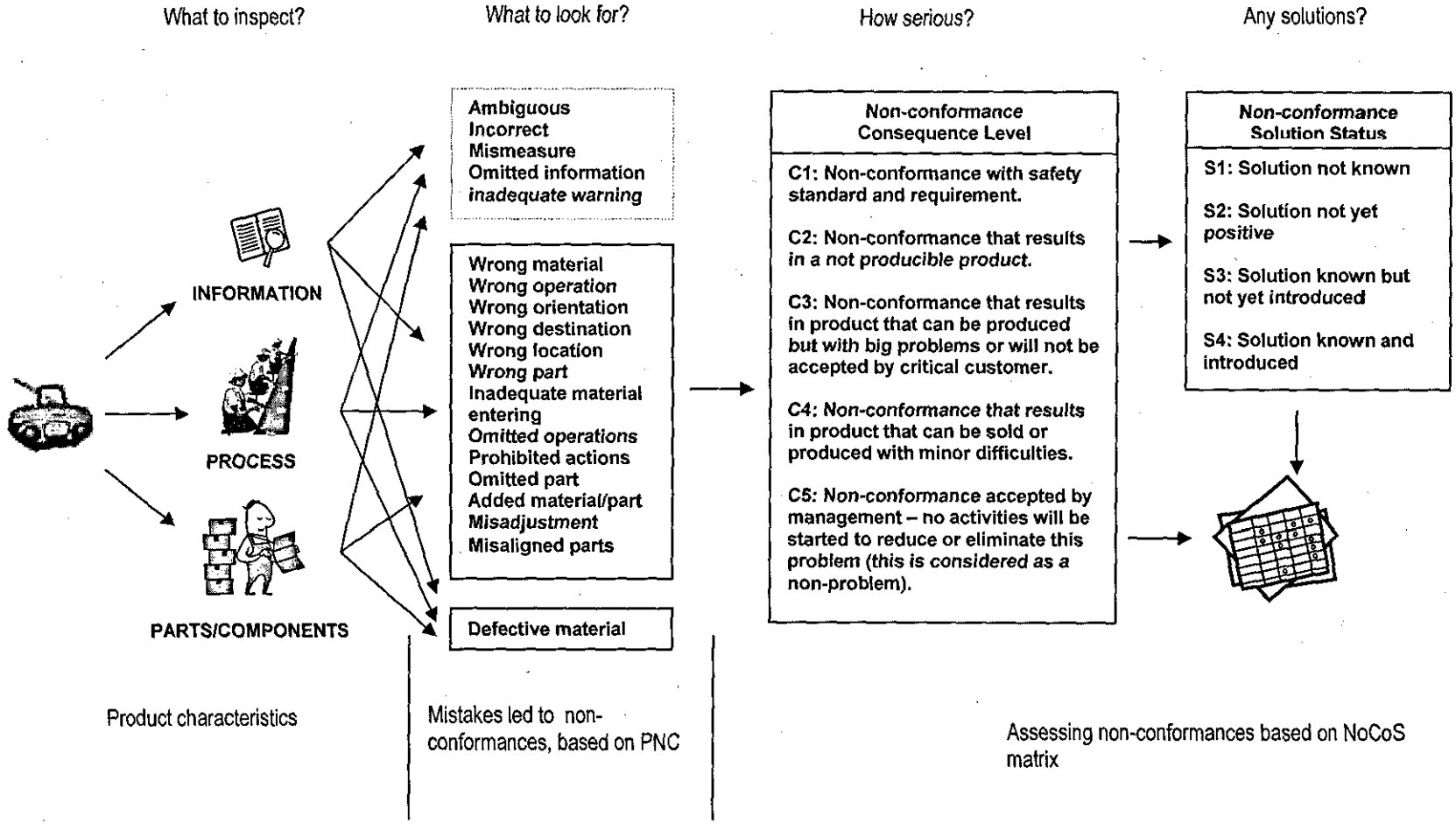


Figure 1-8 Identifying and assessing non-conformances during validation

1.7 Application of Workbook

1.7.1 Users of Workbook

The product validation workbook assists people responsible for validation of products during pre-production. These people are the validation team within a manufacturing facility. The team typically consists of representatives from different functions such as design, production, Quality Control (QC)/Quality Assurance (QA), and engineering. They should hold positions either as designers, engineers and inspectors. The design and engineering function focuses on inspecting out-of-box samples, with the production and QC/QA inspecting the trial-run.

1.7.2 Using Workbook

The validation workbook is to be considered as a pre-production controlled document where it is used, up-dated and disseminated among the relevant people involved in product validation in the company. The pre-production function will be responsible for the maintenance of the workbook. The validation team should read and understand the content of the workbook prior to validation. The workbook should be referred to under three conditions as follows:

1. *Before the start of validation.* Each member of the validation team should abide by the content of the workbook as much as possible. For a new member of the team, if need to, a briefing on the use of the workbook is necessary. The workbook provides readers with a broad idea of the conduct of validation through illustration and explanation of the validation framework, steps and procedure. The *three general rules*, which are key instructions, are to be followed during product inspection and non-conformance assessment. This is important to ensure that the validation team delivers products which are fully inspected, i.e. conform to specification/requirement, and simultaneously non-conformances are identified and rectified. These rules are to be emphasised in a meeting prior to validation, as described in Step 1.

2. *During validation.* Five sequential steps of product validation are described in the workbook to be followed throughout the validation. Two important parts of the workbook will guide the validation team in addressing non-conformances. Firstly, *identifying non-conformances,* the workbook describes three main product characteristics (information, process and parts/components) and the associated cause of non-conformances as the basis for systematic inspection. This has been made simple using the Product-based Non-conformances Classification or PNC, as illustrated in Step 2. An example of an inspection checklist is provided. Secondly, *analysing non-conformances*, the workbook describes non-conformances are to be defined in terms of the severity of its consequences and the condition of the solution. This will provide a consistent assessment. Detailed description of the consequences, and solutions, or Non-conformances and Solution (NoCoS), and their coding are explained in Steps 2 and 3. An example of an inspection summary form in which identified non-conformances are to be classified and logged is provided. Subsequently, logged non-conformances are tabulated into the NoCoS matrix for further scrutiny. Subsequently, non-conformances are to be rectified with appropriate solutions and mistake-proofing implemented as prevention techniques, as given in Step 4.

3. *After validation.* New causes of non-conformances are to be addressed and anomalies with regard to the *workbook format, typology, content (procedure, steps,* and *examples)* are to be amended and improved when necessary. This should be carried out jointly by the key teams responsible in the validation process. This is to ensure that the content of the workbook and validation process has been agreed and abide by validation teams, whilst being continuously improved and up-dated just like any other controlled documents. Hence, only the most recent workbook is to be disseminated and used by the validation team.

1.7.3 Benefits of Workbook

The workbook provides companies with

- a simple, comprehensive and structured validation procedure and guide to be followed by validation team in identifying and controlling non-conformances in pre-production.
- a procedure and guide to be use in validating either new or derivative products were similar, since the basic product characteristics as validation consideration described throughout the procedure were typical.
- an uncomplicated classification of non-conformances based on the cause of non-conformances and their manifestation.
- an assessment method which quantifies non-conformances based on consequences and solution condition tabulated in a straightforward matrix.
- the technicality of the presentation of the workbook is kept to a minimum to cater for broader users and readers within company.
- a training material on product validation, mistakes and non-conformances identification and understanding for existing and new staff.

2. VALIDATION PROCESS

General Rules

Step 1 – Initiation

Step 2 – Detection

Step 3 – Analysis

Step 4 – Rectifications

Step 5 – Verification

2. VALIDATION PROCESS

2.1 General Rules

- As a guideline, the validation process should follow the general rules below:

Rules	Description
100 % Inspection	Ensuring all considerations of product under validation are inspected and not missed out.
Rapid Analysis	Results of inspection investigated and non-conformances rectified rapidly.
Extensive Prevention	Strategy to avoid occurrence of non-conformances, implying both temporary and permanent solutions.

- The product under validation is inspected on three aspects: Information, Process and Parts/Components (see Table 2-1), which correspond to the interrelated characteristics of the finished product, as shown in Figure 2-1. The finished products are:

  - *Engineering Samples* (now known as product) assembled by the design team
  - *Trial-run Samples* assembled by the production line

- The inspection checks tangible non-conformances, or any deviation of specification and quality. The non-conformances are visible and known about by everybody, especially production, and are not merely confined to the Quality Control team [3].

Table 2-1 Three aspects of product validation.

Information	Process	Parts/Components
Standard Procedure *Instruction* Checklist Specification Reviews Drawings Guides	PCB assemblies Sub-assemblies Assemblies Packaging Handling	Packaging Accessories Mechanical parts Electronic parts Electrical parts

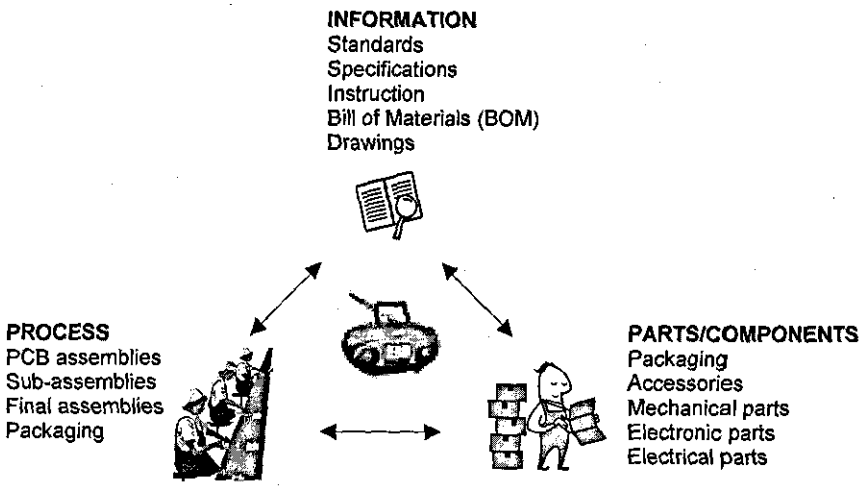


Figure 2-1 Three interrelated product characteristics.

2.2 Step 1 – INITIATION

2.2.1 Purpose

- To ensure that the product, trial-run and related materials are complete.
- To ensure that the validation teams are prepared to conduct the inspection.

The INITIATION step is shown in bold in Figure 2-2.

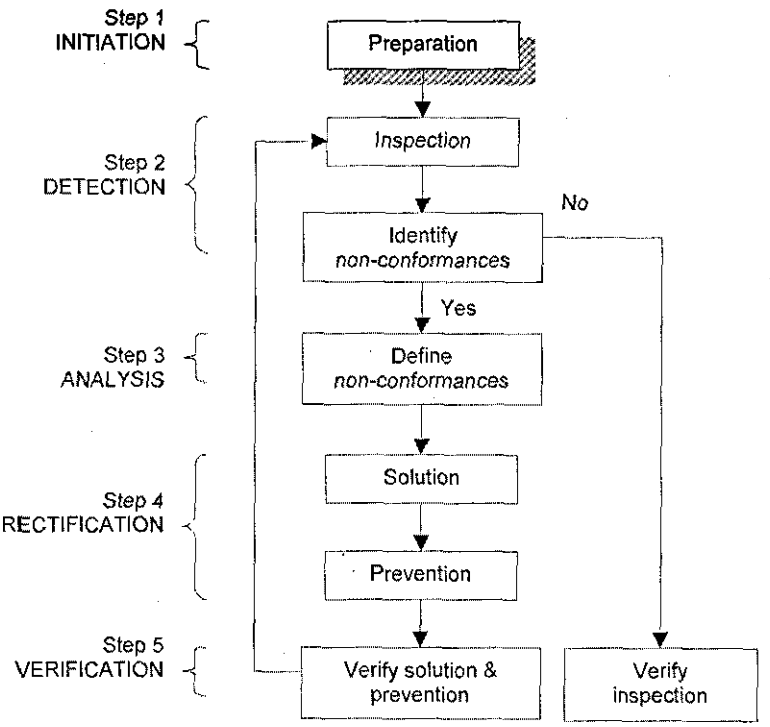


Figure 2-2 Layout of Step 1 – INITIATION.

2.2.2 Procedure

- In the validation model, the elements related to Step 1 are the Product (Input), the Information, Process and Parts/Components (Controls) and the Initiation as part of the validation process (Process), shown in bold in Figure 2-3.

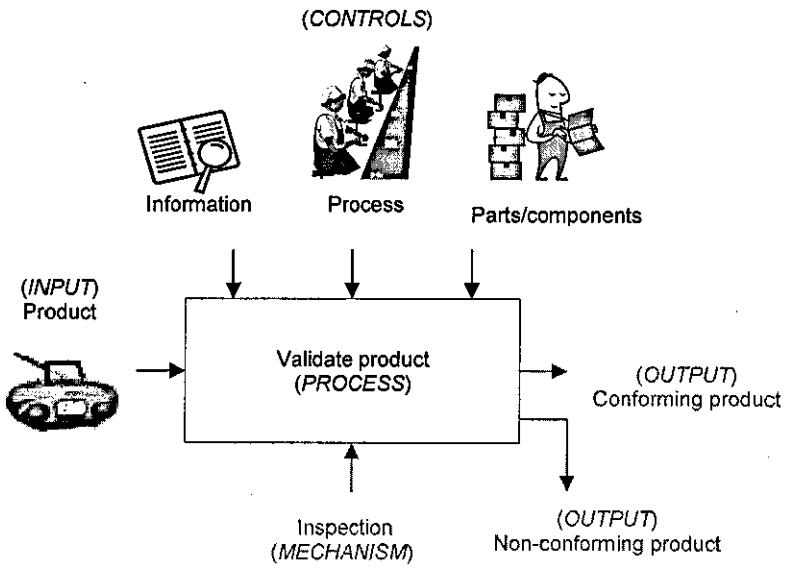


Figure 2-3 Elements related to Step 1.

- A validation meeting is to be arranged which involves the validation teams from the Engineering (mediator), Design and Production functions.

- The validation teams are to carry out the following tasks:

  Engineering and Production teams inspect product,

  Production team arrange trial-run,

  Design team supplies engineering samples and relevant documentation.

- The product and the control items should be complete and the preparation for the trial-run assembly lines ready.

- The product and the relevant materials are to be studied, understood and familiarity gained by each member of the validation teams.

The Step 1 - INITIATION activity is shown in Figure 2-4.

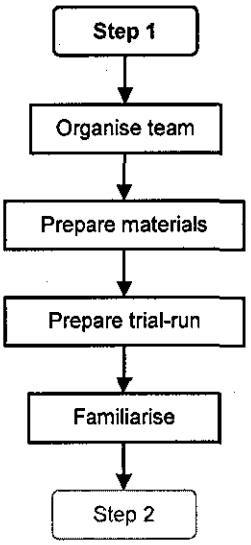


Figure 2-4 Step 1 - INITIATION activities.

2.2.3 Activities

- *Meeting.* A meeting is held to ensure that preparation for the inspection is ready and complete. The validation team at the meeting are representatives from the engineering team, the design team, and the production team. The meeting will clarify who is doing what, when and how.

- *Teams.* The first agenda item of the meeting is to identify the representatives from each team; occasionally, new members are introduced, and the task of each team is described. The meeting is led by the engineering team as moderator in the validation process throughout.

- *Documentation.* The second agenda item is to collect, check and ensure that the product under validation and the relevant materials are to hand, correct and complete. The 'out-of-box' samples are distributed to each team, complete with documentation (e.g. drawings and BOM). A checklist is used to ensure that all items are in order. This is the task of the engineering team.

- *Trial-run.* Before the trial-run starts, all the necessary parts and components to assemble the product are delivered to the production lines. The preparation for producing the products includes setting up the PCB assembly, sub-assembly, final assembly and packaging workstations, according to the standard production protocol. This is the task of the production team.

- *Familiarisation.* The product is introduced to the teams by walk-through. Each member of the team should thoroughly understand and familiarise with the three product characteristics: information, process, and parts/components (see Figure 2-5). Without a thorough understanding, the teams will not be able to contribute effectively to the validation process. The design team is responsible to brief and respond on all matters relating to the product under validation to ensure success of the product's pre-production.

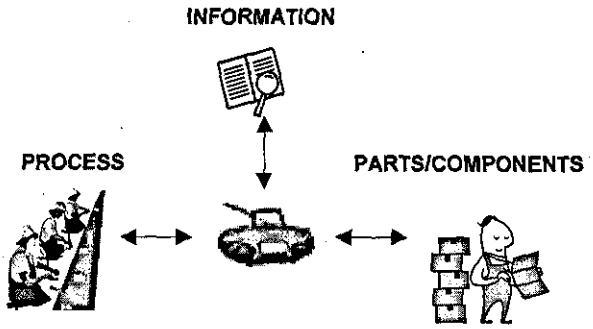


Figure 2-5 Product characteristics for validation team to be familiarised with.

2.3 Step 2 – DETECTION

2.3.1 Purpose

- To ensure that the product and trial-run are inspected rigorously.
- To ensure that non-conformances are not overlooked.
- To ensure that all non-conformances are classified and logged correctly.

The DETECTION step is shown in bold in Figure 2-6.

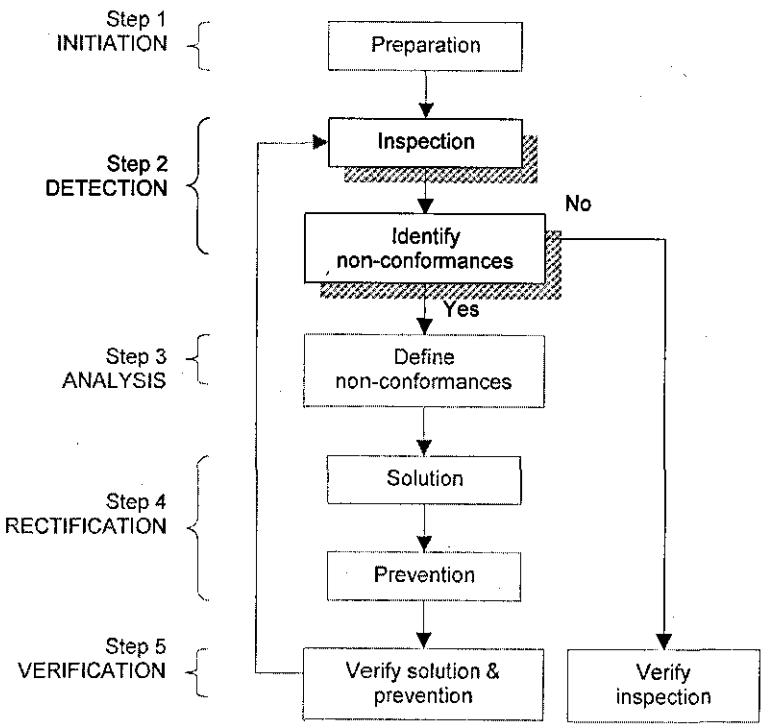


Figure 2-6 Layout of Step 2 - DETECTION.

2.3.2 Procedure

- In the validation model, the elements related to Step 2 are Conforming and Non-conforming Product (Output), Inspection as the means (Mechanism) to identify non-conformances, Detection as part of the validation process (Process), Information, Process and Parts/Components as the inspection reference (Controls), and Product (Input) as the subject of inspection, shown in bold in Figure 2-7.

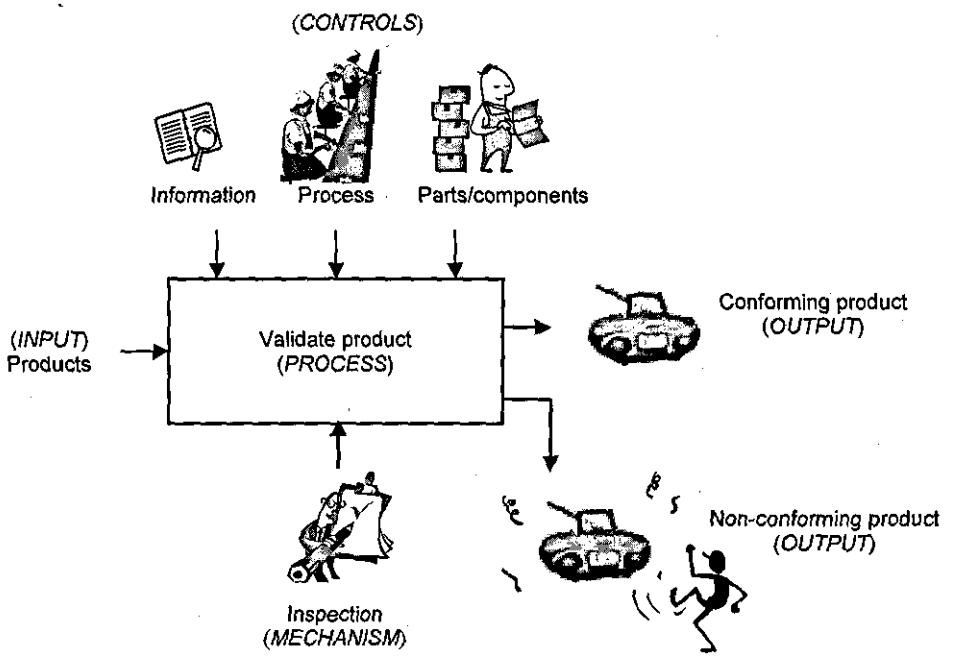


Figure 2-7 Elements related to Step 2.

- A 100% Inspection is to be carried-out on the three product characteristics: Information, Process, and Parts/Components, and checked against each other, shown by dotted arrows in Figure 2-8.

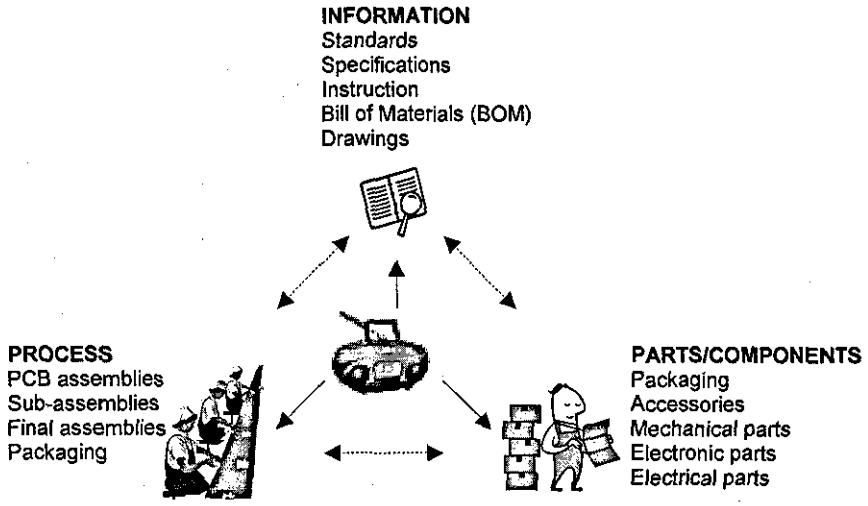


Figure 2-8 Inspection of product characteristics.

- The three product characteristics and their interrelationship are inspected, firstly on the product as out-of-box inspection, and secondly, on the trial-run inspection. This is known as the two-phase inspection, shown in Figure 2-9.

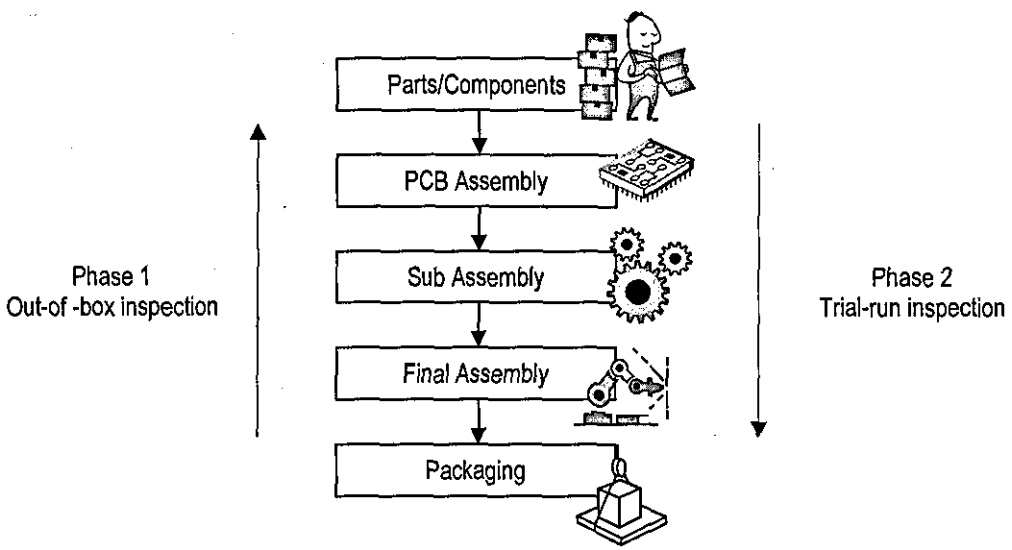


Figure 2-9 Two-phase inspection sequence

- The particulars to be inspected are the items in each of the three product characteristics (see Annexe 1).

- As shown in Table 2-2, the inspection is to identify the non-conformances manifested from mistakes, grouped into three classes:

    1. Information Non-conformances
    2. Process Non-conformances
    3. Parts/Components Non-conformances

This classification is known as the Product-based Non-conformance Classification or PNC, where the non-conformances are associated with the three product characteristics.

Table 2-2 Description of PNC.

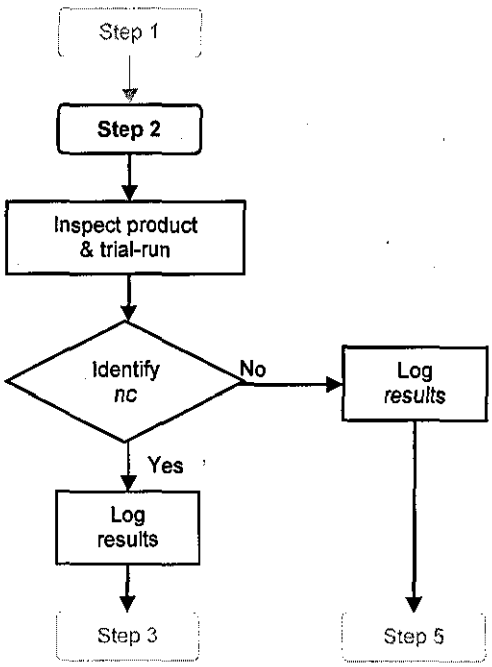
Class of non-conformance	**Locality of non-conformances**	**Type of mistakes**	**Description of mistakes**
INFORMATION	Technical specifications Work instructions Bill-of-materials Drawings Checklist *Engineering* change order	Ambiguous Information	*Information can be interpreted many* ways, some interpretations may be incorrect.
		Incorrect Information	Information provided incorrect.
		Misread, Mis-Measure, Misinterpret	Errors in gauge-reading, errors in measuring, or errors in understanding correct information.
PROCESS	PCB assemblies Sub-assemblies Final assemblies Packaging	Omitted Operations	Failure to perform required operation.
		Wrong Part	Part selected, but wrong part.
		Wrong Orientation	Part inserted in correct location, but *part has wrong orientation.*
		Wrong Operation	Operation executed, but wrong *operation used.*
		Wrong Location	Part insertion or process execution in *incorrect location, not the result of* incorrectly orienting parts.
		Wrong Destination	After completion of an operation, *product sent to wrong address* or destination.
PARTS/ COMPONENTS	*Packaging materials* Accessories Mechanical parts Electronic parts Electrical parts	*Defective* Materials	Material *entering* process is defective, or inadequate for intended function, *process, or purpose.*

- Inspection should also check for other potential mistakes correlated with the classes of non-conformances (see example in Annexe 2).

- Evidence of non-conformances is logged in the INSPECTION SUMMARY FORM.

- If there is no evidence of non-conformances, end the inspection, log the results, and then proceed to Step 5 - INSPECTION VERIFICATION. Otherwise, log any non-conformances identified and proceed to Step 3 – ANALYSIS, as shown in Figure 2-10.

The Step 2 - DETECTION activities are shown in Figure 2-10.



Note: nc = non-conformances

Figure 2.10 Step 2 - DETECTION activities

2.3.3 Activities

Identifying non-conformances

- The detection starts with inspecting all particulars pertaining to the product. A 100% inspection should be carried out on the product's information, process, and parts/components. The inspection instrument is the checklist to be used to identify the manifestation of non-conformances. An example of the checklist is shown below:

Inspection items	*Result*	
Safety/certification labels and marking on back panel	attached	omitted
Safety/certification labels and markings shown 'CE'	correct	incorrect
Safety/certification labels and markings location	correct	incorrect
Safety/certification labels and marking imprint	adequate	inadequate

- The inspection is conducted in two phases. Firstly, the *out-of-box inspection,* where the validation team checks the product against the product's information, process and parts/components. The inspection focuses on

    - accessories items, e.g. remote control, speakers, instruction, etc., all supplied and nothing else
    - cosmetic finish and appearance
    - assembly configuration, e.g. opening/removing cover panels
    - function, feature and operation

- Secondly, the *trial-run inspection,* where the validation team checks the assembly activities in delivering a conforming product. The inspection focuses on

    - parts/components used to assemble the product
    - assembly aids such as assembly drawings and work instructions
    - assembly operations which are the PCB assemblies, sub-assemblies, final assemblies, and the packaging

- An example of a non-conforming item and the possible mistakes are shown in Annexe 3.

Logging non-conformances

- A simple-to-use form is used to log the evidence of non-conformances. An example of part of the Inspection Summary Form is in shown in Figure 2-11, where identified non-conformances are recorded and described with unique codes. The completed form consists of all the results and evidence of non-conformances.

INSPECTION SUMMARY FORM

Reference No	: **ISF 0001**	*Date*	: **01/01.2007**
Product	: **XYZ**	*Version*	: **0.1**
Document	: **Checklist SAFETY 1**	*Inspector*	: **Mr. X**

Activity : ☐ Check Product ☐ **Check trial-run**

Particulars :

☐ Packaging	☐ Accessories	☐ **Safety**
☐ External	☐ Internal	☐ Documents
☐ Mechanical	☐ E & E	☐ PCB
☐ Assembly	☐ Sub-assembly	☐ Others

Location : Rear panel

Part	*Description*	*Type**	*NC*	*CON*	*SOL.*
Cert. Label	1. label omitted.....	OMP	...	.....	.....
.....	2. CE marking incorrect	INI	...	.....	.....
.....	3. label location incorrect.....	WRP	...	.....	.....
.....	4. label print inadequate.....	AMI	...	.....	.....
.....	.....	.....	....	.....	.....
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** Coding and meanings on next page*

Figure 2-11 Example of logging non-conformances in Inspection Summary Form

Coding and classes of non-conformances and related mistakes

IN Information		*PR* Process		*PC* Parts/components	
AMI	Ambiguous information	*AM*	Added material or part	*DME*	Defective material entering
INI	Inadequate warning	*CPA*	Commit prohibited actions		
INW	Incorrect information	*COE*	Counting errors		
MIS	Mismeasurement	*IME*	Inadequate material entering		
OMI	Omitted information	*MSP*	Misaligned parts		
		MID	Misadjustment		
		OMO	Omitted operations		
		OMP	Omitted part		
		WRM	Wrong material		
		WRD	Wrong destination		
		WRL	Wrong location		
		WRO	Wrong operation		
		WRP	Wrong part		
		WRR	Wrong orientation		

Non-conformance Consequence (CON) and Solution (SOL) coding and description

CON *Consequence*	**C1 :** non-conformance with **safety** standard and requirement. **C2 :** non-conformance that results in product **not producible**. **C3:** non-conformance that results in a product that can be produced but with big problems or will not be accepted by a **critical** customer. **C4 :** non-conformance that results in product that can be sold or produced with **minor** difficulties. **C5 :** non-conformance **accepted** by management – no activities will be started to reduce or eliminate this problem
SOL Solution Status	**S1** : solution not known **S2** : solution not yet positive **S3** : solution known but not yet introduced **S4** : solutions known and introduced

End

Figure 2-11 (continued)

2.4 Step 3 – ANALYSIS

2.4.1 Purpose

- To ensure that non-conformances are analysed correctly.
- To ensure that non-conformances are defined accurately.

The ANALYSIS step is shown in bold in Figure 2-12.

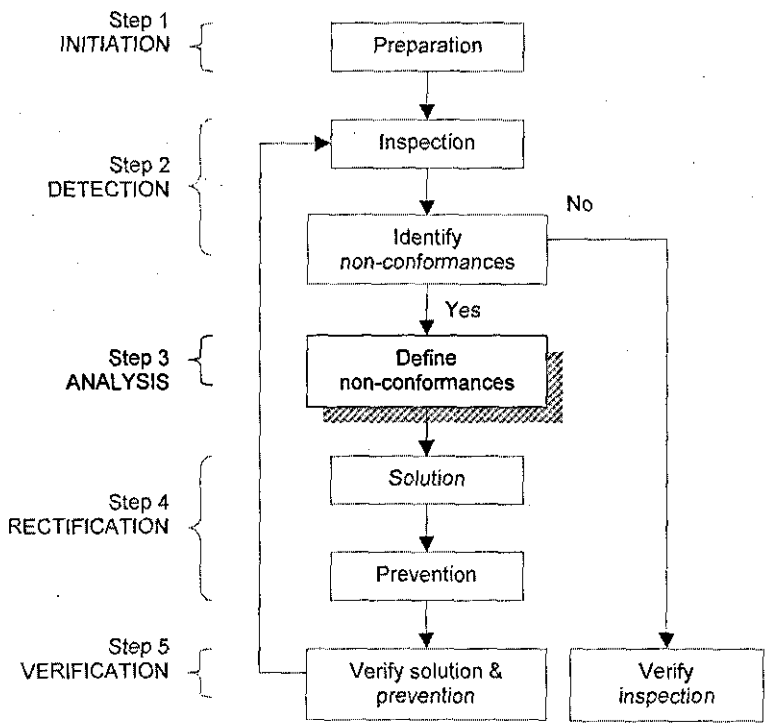


Figure 2-12 Layout of Step 3 - ANALYSIS

2.4.2 Procedure

- In the validation model, elements related to Step 3 are the Conforming and Non-conforming Product (Output), and the Analysis as part of the product validation processes (Process), shown in bold in Figure 2-13.

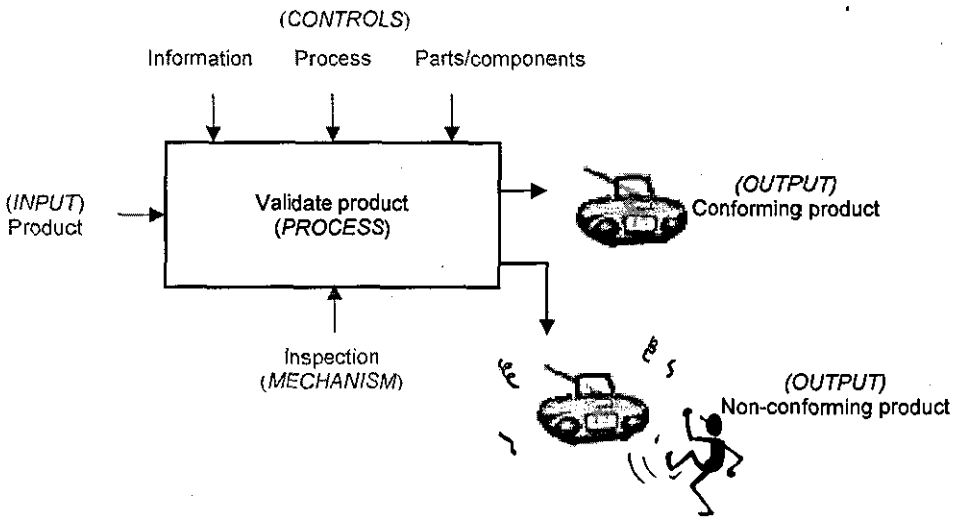


Figure 2-13 Elements related to Step 3.

- A meeting is to be held to define the non-conformances according to the Product-based Non-conformances Classification (PNC) and the Non-conformance Consequence and Solution (NoCoS) methodology.

NoCoS Methodology

- Non-conformances are analysed and prioritised, described in Figure 2-14(a), according to:
  1. consequence to safety, producibility, and customer perception.
  2. solution status, whether a known or unknown solution.

- The Non-conformances Consequence/Solution (NoCoS) matrix is used to analyse non-conformances, described in Figure 2-14(b).

- Non-conformances in the Inspection Summary Form are coded with Consequence Level and Solution Status, then the number of appearances of the codes is entered into the respective cells in the NoCoS matrix (see Figure 2-14(b)).

	Coding/description
Consequence Level	**C1 :** non-conformance with **safety** standard and requirement. **C2 :** non-conformance that results in product **not producible**. **C3:** non-conformance that results in product that can be produced but with big problems, or will not be accepted by **critical** customer. **C4 :** non-conformance that results in product that can be sold or produced with **minor** difficulties. **C5 :** non-conformance **accepted** by management – no activities will be started to reduce or eliminate this problem
Solution Status	**S1** : solution not known **S2** : solution known but not yet positive **S3** : solution known but not yet introduced **S4** : solutions known and introduced

Figure 2-14(a) NoCoS consequence level, solution status, coding and description

		Non-conformance Consequence Level				
		C1	C2	C3	C4	C5
Solution Status	S1					
	S2					
	S3					
	S4					

Figure 2-14(b) NoCoS matrix

The Step 3 - DETECTION activities are shown in Figure 2-15.

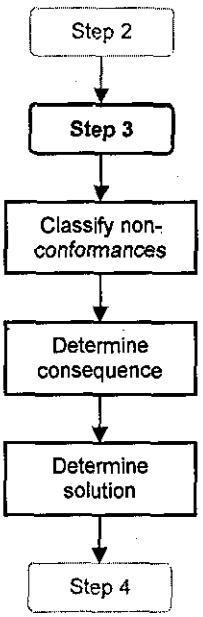


Figure 2-15 Step 3 ANALYSIS activities.

2.4.3 Activities

- A meeting is conducted to analyse the non-conformances identified during Step 2 Detection and entered into the Inspection Summary Form. The evidence of non-conformances from the inspection forms, as well as the physical evidence, is to be studied by the validation teams.

Classifying Non-conformances

- Based on the PNC, the non-conformances which result from mistakes are classified as information, process, and parts/components non-conformances, as shown in Table 2-3.

Table 2-3 Classes and location of non-conformances, and mistakes.

Class of non-conformance	Locality of non-conformances	Type of mistakes
INFORMATION	Technical specifications Work instructions Bill-of-materials Drawings Checklist Engineering change order	Ambiguous Information Incorrect Information Misread, Mis-Measure, Misinterpret Omitted Information
PROCESS	PCB assemblies Sub-assemblies Final assemblies Packaging	Added material or part Prohibited actions committed Counting errors Inadequate material entering Misaligned parts Misadjustment Omitted operations Omitted part Wrong material Wrong destination Wrong location Wrong operation Wrong part Wrong orientation
PARTS/ COMPONENTS	Packaging materials Accessories Mechanical parts Electronic parts Electrical parts	Defective Materials

- In the Inspection Summary Form, the classification of the non-conformances is shown by unique codes:

  IN: information non-conformance,

  PR: process non-conformance,

  PC: parts/components non-conformance.

- An example of the non-conformances classified in the inspection form is shown in bold in Figure 2-16, where unrelated classes are struck out.

Inspection Summary Form

Part	*Description*	*Type*	*NC*	*CON*	*SOL*
Cert. Label	**1. label omitted**	**OMI**	**IN/~~PR~~/~~PG~~**	.....	.....
.....	**2. CE marking incorrect**	**INI**	**~~IN~~/PR/~~PG~~**	.....	.....
.....	**3. label location incorrect**	**WRP**	**~~IN~~/PR/~~PG~~**	.....	.....
.....	**4. label print inadequate**	**AMI**	**IN/~~PR~~/~~PG~~**	.....	.....

Note: NC = Non-conformance

Figure 2-16 Logging classes of non-conformances in Inspection Summary Form

Determining Non-conformance Consequences

- Next, the validation team will determine the consequence of non-conformance based on the consequence level, as shown in Figure 2-13(a), based on the NoCoS methodology. Decisions are based on archives records and the validation team's experiences.

- In the Inspection Summary Form, the non-conformance consequences are described in unique codes, as shown in bold in Figure 2-17.

Inspection Summary Form

Part	*Description*	*Type*	*NC*	*CON*	*SOL.*
Cert. Label	**1. label omitted**	OMI	IN/~~PR~~/~~PG~~	**C1**	.....
.....	**2. CE marking incorrect**	INI	~~IN~~/PR/~~PG~~	**C1**	.....
.....	**3. label location incorrect**	WRP	~~IN~~/PR/~~PG~~	**C1**	.....
.....	**4. label print inadequate**	AMI	IN/~~PR~~/~~PG~~	**C1**	.....

Note : CON = Consequence.

Figure 2-17 Logging non-conformance consequences in Inspection Summary Form

Determining Non-conformance Solutions

- Then, the validation team will determine the non-conformance solution based on the solution status, as shown in Figure 2-13(a). Non-conformances with known solution with status S3 or S4 are qualified to move to Step 4 – Rectification. Non-conformances with unknown solution or new ones with status S2 are handed over to the design team to solve.

- In the Inspection Summary Form, the non-conformance solutions are described with unique codes, as shown in bold in Figure 2-18.

Inspection Summary Form

Part	*Description*	*Type*	*NC*	*CON*	***SOL.***
Cert. Label	**1. label omitted**	OMI	IN/~~PR/PC~~	C1	**S4**
.....	**2. CE marking incorrect**	INI	~~IN~~/PR/~~PC~~	C1	**S3**
.....	**3. label location incorrect**	WRP	~~IN~~/PR/~~PC~~	C1	**S3**
.....	**4. label print inadequate**	AMI	IN/~~PR/PC~~	C1	**S2**

Note: SOL = Solution

Figure 2-18 Logging non-conformance solutions in Inspection Summary Form

NoCoS matrix

- From the Inspection Summary Form, the accumulated coded data on the consequences 'CON', and the solutions 'SOL' are transferred into the appropriate cells in the NoCoS matrix, as shown in bold in Figure 2-19.

Inspection Summary Form

Part	*Description*	*Type*	*NC*	***CON***	***SOL.***
Cert. Label	**1. label omitted**	OMI	IN/~~PR/PG~~	**C1**	**S4**
.....	**2. CE marking incorrect**	INI	~~IN~~/PR/~~PG~~	**C1**	**S3**
.....	**3. label location incorrect**	WRP	~~IN~~/PR/~~PG~~	**C1**	**S3**
.....	**4. label print inadequate**	AMI	IN/~~PR/PG~~	**C1**	**S2**

(a)

		Non-conformance Consequence Type				
		C1	C2	C3	C4	C5
Solution Status	S1					
	S2	**1**				
	S3	**2**				
	S4	**1**				

(b)

Figure 2-19 Data (CON and SOL) from inspection form (a) transferred to NoCoS matrix (b)

2.5 Step 4 – RECTIFICATION

2.5.1 Purpose

- To ensure that all non-conformances are rectified appropriately.
- To ensure that the solution and prevention are deployed correctly.

The RECTIFICATION step is shown in bold in Figure 2-20.

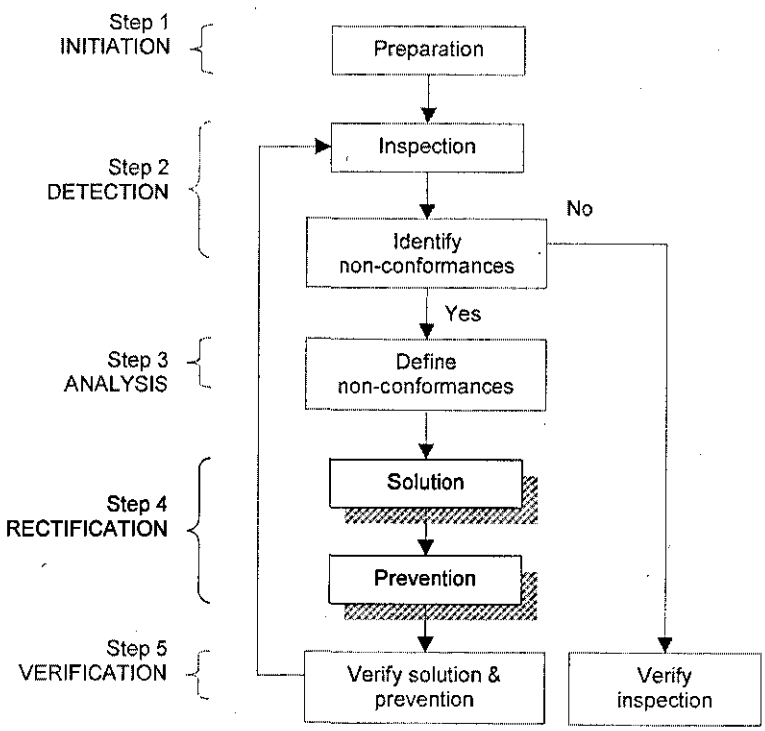


Figure 2-20 Layout of Step 4 - RECTIFICATION

2.5.2 Procedure

- In the validation model, the elements related to Step 4 are the Non-conforming Product (Output) and Rectification, as one of the validation processes (Process), shown in bold in Figure 2-21.

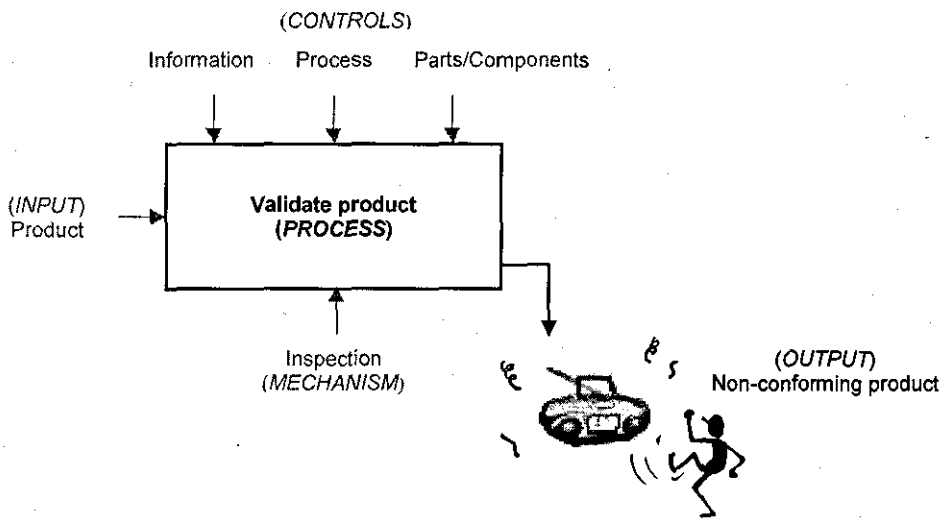


Figure 2-21 Elements related to Step 4.

- Continuing from Step 3, the meeting's second agenda item is to rectify the non-conformances by deploying the solutions and preventions.

- Non-conforming items which have known solutions are implemented rapidly, while the unknown solutions are to be formulated collectively by the validation team. Prevention strategy may be formulated using techniques such as mistake-proofing [4], as in the examples in Annexes 4 and 5.

- In Steps 3 and 4, collective input from the validation team is necessary so that solution and prevention are extensive.

The Step 4 - RECTIFICATION activities are shown in Figure 2-22.

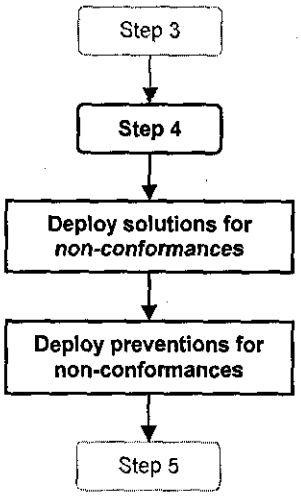


Figure 2-22 Step 4 - RECTIFICATION activities

2.5.3 Activities

- Continuing from Step 3, the meeting's second agenda item is to rectify the non-conformances which have been classified and defined during Step 3 Analysis.

Deploying Solutions

- Table 2-5 illustrates the example of the NoCoS matrix for the non-conformance severe level C1, i.e. product safety. With various known solutions (S2, S3 and S4), they can be deployed promptly. Non-conformances with the severe level C1, without known solution (S1), are to be formulated by the members of the validation team as each member contributes from different perspectives; consequently, rectification is more extensive.

- The permanent solution is deployed on the subsequent improvement to the product, whilst the temporary solution is deployed on the initial batch of production. An example of the deployment of the solution is illustrated in Figure 2-23.

Table 2-5 Non-conformances in NoCoS matrix.

		Non-conformance Consequence Level				
		C1	C2	C3	C4	C5
Solution Status	S1					
	S2	**1**				
	S3	**2**				
	S4	**1**				

Deploying Prevention

- The prevention is to be deployed in both the temporary and permanent solutions, to ensure non-conformances will not escape into a subsequent stage. Mistake-proofing [4] principles and approaches are recommended as a prevention strategy. The principles are

    - make it easier to discover the problems that occur,
    - make wrong actions more difficult,
    - make incorrect actions correct,
    - make it possible to reverse actions - to 'undo' them - or make it harder to do what cannot be reversed.

- To illustrate the deployment of the rectification, using the example of the missing part as shown in Figure 2-23, known solutions and preventions are deployed on the product's information, process and parts/components.

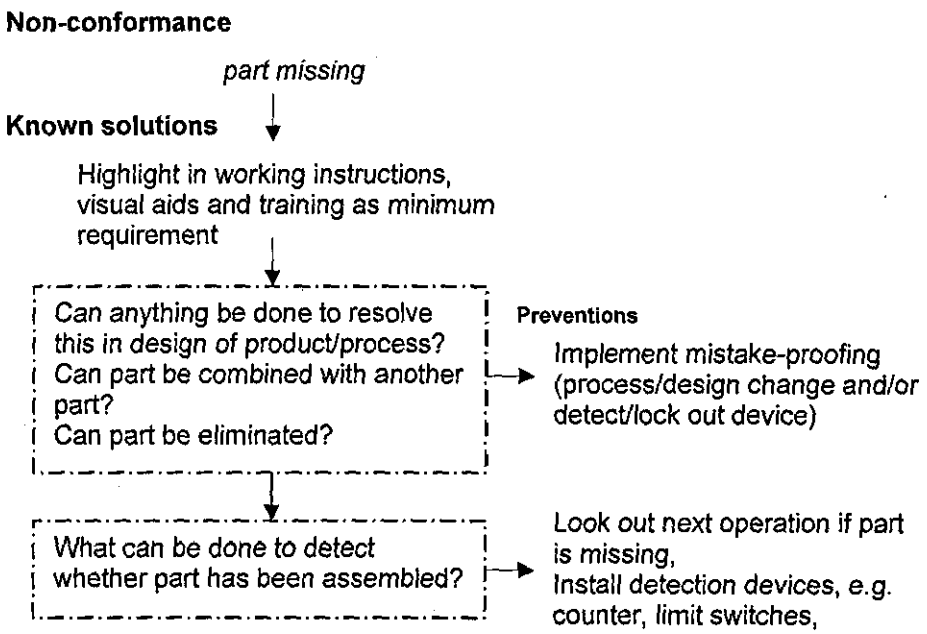


Figure 2-23 Deploying solutions and preventions

- Other examples of non-conformance solutions and preventions are shown and illustrated in Annexes 5 and 6.

2.6 Step 5 – VERIFICATION

2.6.1 Purpose

- To confirm that that Steps 1, 2, 3 and 4 are complete and executed correctly.

The VERIFICATION step is shown in bold in Figure 2-24.

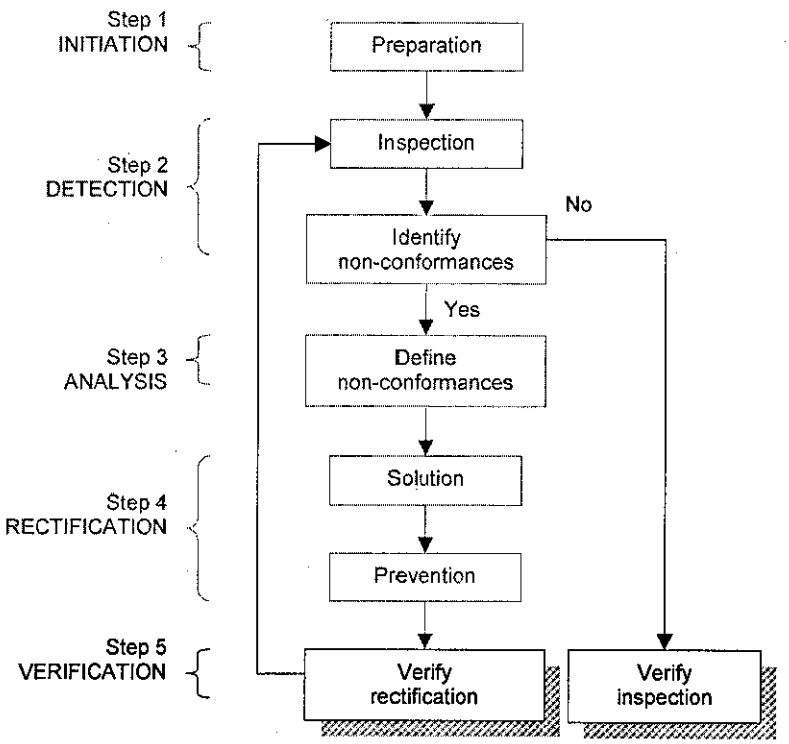


Figure 2-24 Layout of Step 5 – VERIFICATION

2.6.2 Procedure

- In the validation model, the elements related to Step 5 are Conforming and Non-conforming Product (Output) and Verification, as one of the validation processes (Process), shown in bold in Figure 2-25.

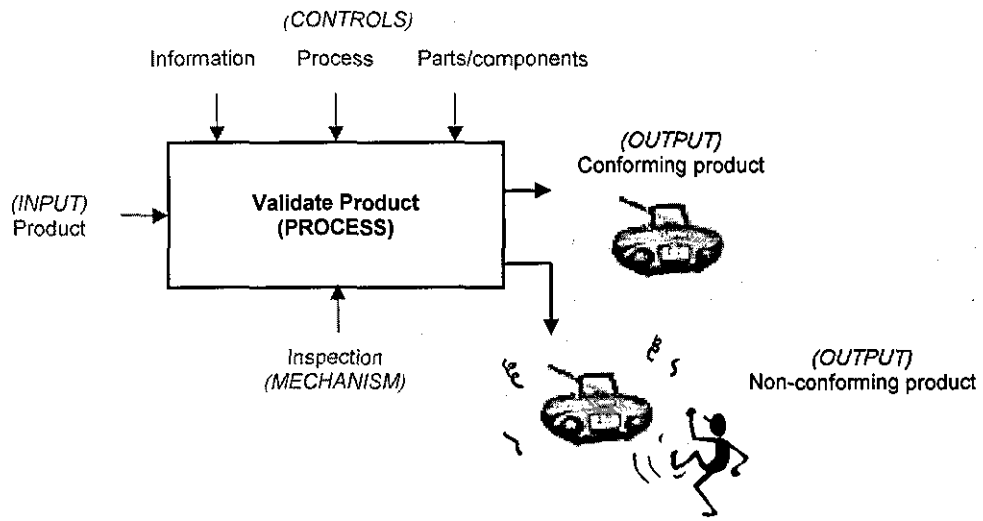


Figure 2-25 Elements related to Step 5.

- A meeting is conducted with two agenda items:

  1. To verify completion of Step 1 - INITIATION, and Step 2 - INSPECTION activities.
  2. To verify completion of Step 1 - INITIATION, Step 2 - INSPECTION, Step 3 - ANALYSIS, and Step 4 - RECTIFICATION activities.

- The INSPECTION VERIFICATION is performed after Step 1 - INITIATION and Step 2 - DETECTION are completed. The product is totally without any non-conformances being identified, and is in conformance with the stipulated product information, process and parts/components.

- The RECTIFICATION VERIFICATION is performed after Steps 1, 2, 3 and 4 are completed. The non-conformances are identified, analysed, the correction and prevention plan is deployed, and the product is re-validated.

- The validation team are required to confirm that the validation process has been executed correctly and documented appropriately. The verification is the last step and completes the validation process.

The Step 5 - VERIFICATION activities are shown in Figure 2-26.

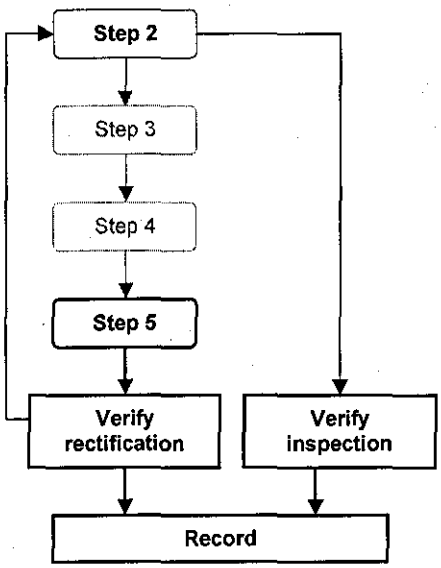


Figure 2-26 Step 5 - VERIFICATION activities.

2.6.3 Activities

Verifying Inspection

- Upon the completion of Steps 1 and 2, the validation team decides to **ACCEPT** the product and trial-run, on condition that the inspection results show no evidence of non-conformances. The product and trial-run satisfy the conformances criteria to qualify the product for full-scale production. Hence, this completes the validation activity.

Verifying Rectification

- Upon the completion of Steps 3 and 4, the validation team decides to **CONDITIONALLY ACCEPT** the product and trial-run on the condition that the evidence of non-conformance has been corrected and the prevention plan has been deployed. The product and trial-run require re-validation until they satisfy the conformance criteria to qualify the product for full-scale production.

- The validation team collectively signs the verification document or the 'memorandum of agreement' (MOA). This document is the evidence of a common understanding and agreement about the condition of the product and the conduct of the validation process.

Documenting validation process

- The records on the validation activities, the non-conformances identified in the product and trial-run, the solutions and preventions deployed, and the decisions made are to be compiled and documented. This document will be used as a reference for future development, reviews and improvements. Documenting the validation process is the last task of the verification activity.

- The meeting contributes to the awareness and learning experiences of the problems, solutions and preventions regarding the product under validation, and for subsequent product validation and development activities.

REFERENCES

ANNEXES

REFERENCES

[1] Hinckley, C.M. (2001), *Make No Mistake: An Outcome-based Approach to Mistake-proofing.* Portland, OR: Productivity Press.

[2] *Standard for Integration Definition for Function Modelling - IDEF0* (1993), Federal Information Processing Standards Publications (FIPS PUBS). Gaithersberg, MD: National Institute of Standards and Technology.

[3] Yuan, L. (2002), *Analysing Reliability Problems in Concurrent Fast Product Development Processes,* PhD Thesis, National University of Singapore.

[4] Shingo S. (1986), *Zero Quality Control: Source Inspection and the Poka-yoke System.* Translated by Dillon, A.P. Stanford: Productivity Press.

ANNEXE 1 – List of items to be validated (Step 2)

a. INFORMATION

Drawings	▪ Complete set of most recently approved assembly, detail and working drawings. ▪ Information on drawings identification, i.e. drawing number, title, page number, etc., dimensions, notes, amendments, symbols, conventions, etc.
Bill of Materials (BOM)	▪ Most recent approved documents with complete list of mechanical and electronic parts and components, and sub-assemblies.
Packaging	▪ Printed identifiable product information, i.e. labels, graphics, colour, languages, instructions, messages, numbers, characters on carton boxes, plastic/paper wrappers and polystyrene-foams, bar-coded product information, etc. ▪ Safety information on carton boxes, plastic wrappers, and polystyrene foams, i.e. weight, size, handling orientation, stacking guides, safety messages and instructions, etc. ▪ Complete set of accessories printed materials. ▪ Instructions, manuals, booklets, warranty card, reply cards, etc. for all accessories with part name and part numbers, labelled, correct languages on printed materials.
Product Safety	▪ Assembled, sub-assembled parts, mechanical and electronic components clearly labelled or imprinted with safety messages, warnings and instructions in compliance with safety standards and specifications.
External and Internal Panel	▪ Brand logo, model identification (name of model and unique number on stickers or imprinted); labelling for functions and features (e.g. power on-off, volume, left/right, etc.). ▪ Dismantling instructions, messages, warnings and instructions all around and inside the product.
Parts/Components	▪ To tally with detail and assembly drawings, e.g. dimensions, type of material, colour, etc.
Testing and Measurement	▪ Testing and measuring electronic and electrical values as per specification and safety requirements. ▪ Quality and reliability testing and measurement including information for packaging specification.

(continued)

ANNEXE 1 (continued)

b. PROCESS

PCB assemblies	▪ Both automated and manual insertions, e.g. new and additional components, components to be removed or replaced.
Sub-assemblies	▪ Sub-assembled parts, e.g. product modules, CD/Cassette drivers, PCBs. ▪ Fitting of loose parts, e.g. bolts/nuts, plastic fasteners, joints, brackets, housings, washers, wiring, lids, bases, etc.
Final assemblies	▪ Fitting all sub-assembled parts and modules according to procedures, with special care.
Packaging	▪ Packing of items with packaging materials using appropriate methods, sequence and orientation of packaging.

c. PARTS/COMPONENTS

Packaging configuration	▪ Carton boxes. ▪ Plastic wrappings for product and accessories. ▪ Polystyrene foam (protecting product). ▪ Packing seals and cushioning (bubble packs).
Accessories	▪ Complete set of printed materials, i.e. warranty cards, reply cards; manuals, instructions booklets. ▪ Complete set of accompanying items, i.e. remote controls, cables, loud speakers, batteries, antenna, and other related items.
Product	▪ Physical and appearance. ▪ Casings (front panel, rear panel base lids, and battery lids), colour, materials, stickers, etc. ▪ Moving mechanism, i.e. buttons, CD trays, sliders, cassette decks, antenna, handles, knobs and other parts. ▪ Cables and fittings, i.e. power supply, external antenna, speakers, microphone and headphone. ▪ Mechanical and electronic assemblies. ▪ Fittings, housings, brackets, fasteners, joints. ▪ PCBs (main board, tuner board, AV boards), LEDs, miniature components, wire harnesses, displays, motors, cables and wiring connections, etc.
Functionality	▪ Conditions and features as per requirements and working together with accessories.
Safety	▪ Visual, audible and tactile check on mechanical parts, i.e. sharp and pointed edges, loose assemblies, breakages, foreign materials, etc. ▪ Visual and audible inspection, and testing on wiring and cables insulations, labels, colour codes, warning signs, jacks and insertion, LEDs, etc.

ANNEXE 2 List of mistakes related to three classes of non-conformances (Step 2)

(adapted from Hinckley, 2001).

⊙ Strong Connection
O Connection
Blank Weak/No Connection

		P/C	Information					Process												
		Defective material	Ambiguous	Incorrect	Mismeasurement	Omitted information	Inadequate warning	Misalignment	Misadjustment	Mistimed	Added parts	Prohibited act	Omitted operation	Omitted parts	Concept or material	Destination error	Location error	Operation error	Parts error	Orientation error
P/C	Defective Material							O	⊙	⊙		O	⊙	⊙				⊙	⊙	⊙
Information	Ambiguous				⊙			⊙	⊙				O				O	⊙	⊙	O
	Incorrect				⊙				⊙	⊙		⊙			O	⊙		⊙		
	Mismeasurement	O	⊙	O				⊙	⊙	⊙					⊙		O			O
	Omitted information							O	O			⊙	O	O	⊙		O	O	O	
	Inadequate warning							⊙	⊙	⊙										
Process	Misalignment	O	⊙		⊙	O	⊙		⊙	⊙			O	O			⊙			⊙
	Misadjustment	⊙	⊙	⊙	⊙	O	⊙	⊙		⊙		O					O			O
	Mistimed	⊙		⊙	⊙		⊙	⊙	⊙			O	⊙	⊙		O	O	O	O	O
	Added parts											⊙		O					O	
	Prohibited act	O		⊙		⊙			O	O	⊙				O					
	Omitted operation	⊙	O			O		O		⊙				⊙	⊙			⊙		
	Omitted parts	⊙				O		O		⊙	O		⊙				O	O	O	
	Concept or material			O	⊙	⊙						O	⊙					⊙	⊙	
	Destination			⊙						O							⊙		⊙	
	Location error		O		O	O		⊙	O	O				O		⊙		O	O	⊙
	Operation error	⊙	⊙	⊙		O				O			⊙	O	⊙		O		⊙	⊙
	Parts error	⊙	⊙			O				O	O			O	O	O	O	O		O
	Orientation error	⊙	O		O	O		⊙	O	O							⊙	⊙	O	

ANNEXE 3 – Example of mistakes related to product safety (Step 2)

Type of Non-conformances			*Parts/Components*	*Information*					*Process*												
Particular	Part	Item	Defective material entering	Ambiguous information	Incorrect information	Mismeasurement	Omitted information	Inadequate warning	Misaligned parts	Misadjustment	Added material or part	Prohibited act	Omitted operation	Omitted part	Counting errors	Wrong material	Wrong destination	Wrong location	Wrong operation	Wrong part	Wrong orientation
Safety	Label	Carton box			◉		◉	◉													
		Plastic wrapper			◉		◉	◉													
		Rear Panel			◉		◉	◉													
	Electrical	Power Cord	◉	○				○								◉				◉	○
		Wire Harness	◉						◉		◉			◉		◉	○	○	○	◉	◉
		Cord Clamp	◉							○				◉		◉		○		◉	◉
		Tie Band	◉						◉	○	◉	○	◉	◉	○	◉	○	◉	◉	◉	◉

Legend
◉ high probability
○ low probability

ANNEXE 4 Examples of mistakes and mistake-proofing techniques (Step 4).

a. INFORMATION

NC	Description	MISTAKE-PROOFING APPROACH
AMBIGUOUS INFORMATION	Information can be interpreted many ways, some interpretations may be incorrect.	1. Where possible, simplify task, instruction, or specification. • Minimise number and similarity of parts and tools. • Identify and remove unnecessary material using red tags/marks. • Minimise number and complexity of operations. • Make instruction brief and graphic. • Minimise or eliminate need to add up dimensions and tolerances to fabricate parts. 2. Make labels, messages, instructions, and controls easy to see, read, and reach. 3. Limit amount of information available. 4. Make various types of information distinctly different. • Visual-group related items and distinguish by colour. 5. Use pictures, videos, graphics, or drawings to identify complex parts and clarify complex operations.
INCORRECT INFORMATION	Information provided incorrect.	1. Prevent spurious information. 2. Ensure that instructions cannot be skipped or repeated. 3. Use checklist to verify that results match predictions or requirements. 4. Review instructions and information for accuracy. 5. Have several individuals with diverse backgrounds review instructions and specifications to identify and eliminate potential ambiguity. 6. Look-alike parts must have drawing numbers that differ.
MISREAD, MISMEASURE, OR MISINTERPRET	Errors in gauge-reading, measuring, or in understanding correct information.	1. Make interpretation easy: • Drawings, pictures, or videos illustrate complex parts, concepts, or operations. 2. Print required dimension guide on worksheet.

(continued)

ANNEXE 4 (*continued*)

b. PROCESS

NC	Example	MISTAKE-PROOFING APPROACH
OMITTED PARTS AND COUNTING ERRORS	*Missing part or wrong number* of parts resulting from counting error.	1. Eliminate parts by combining functions with other parts. 2. Make part omission errors and counting errors obvious. 3. Layout makes missing parts obvious (remainder *method*). 4. Prevent an operation if part missing.
OMITTED OPERATIONS	*Failure to perform required* operation.	1. *Prepare standard procedure charts.* 2. Create and use operation checklist. 3. Eliminate need for operation, e.g. by simplifying product or process. 4. Make omitted operations visible and obvious, e.g. detect omission of operation by comparison to correctly completed items
WRONG PART	*Part selected, but it wrong* part.	1. Change design so that same part can be used in right- and left-hand locations. 2. Look-alike parts at each work station minimised, *eliminated, or non-interchangeable.* 3. Interference prevents assembly of similar but wrong part. 4. *Identical* parts made of *dissimilar material clearly* marked.
WRONG ORIENTATION	Part inserted in correct location, but part has wrong orientation.	1. Where possible, make parts symmetrical, e.g. end-to-end symmetry. 2. Make parts asymmetric, and make asymmetry obvious (shape/dimension), 3. Interference prevents set-up or assembly of *asymmetrical parts in wrong orientation.*
WRONG OPERATION	Operation executed, but wrong operation used.	1. Mistake-proof selection of instructions, have only one instruction visible at a time. 2. Single design used for both right and left hand parts. 3. Redesign, making control setting easy to read. 4. Standard procedure chart guides selection of correct operation.
WRONG LOCATION	Part insertion or process execution in incorrect location not results of incorrectly *oriented parts.*	1. Simplify design to eliminate inserting (retrieving) parts or materials in wrong location. 2. *Change design so that one part fits all locations.* 3. Reduce types of fasteners. 4. Interference prevents insertion in wrong location (*shape or dimensions*). 5. Asymmetrical pin and hole pattern allows only one location. 6. Variety of parts, each has unique shape and mating insertion feature. 7. Interference detects defect. 8. Different cable lengths on wiring harness allow only correct connections.
WRONG DESTINATION	After completing operation, product sent to wrong address or destination	1. Keep destination information linked with product.
WRONG CONCEPT	Design-decision errors *resulting in incompatible* materials, hazardous products, non-functional products, or any one of wide range of problems. Such errors can also result in products subject to excessive wear, not robust, unreliable, or unsatisfactory to customers.	1. Develop and maintain design checklists unique to specific products. 2. *Button and switch locations easy to see, and labels* easy to read 3. Parts have adequate constraints 4. Parts accessible for disassembly and maintenance

(continued)

ANNEXE 4 (continued)

c. PARTS/COMPONENTS

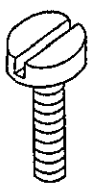
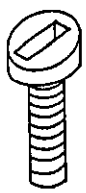
NC	Example	MISTAKE-PROOFING APPROACH
DEFECTIVE MATERIALS	Material *entering* a process defective, or inadequate for *intended function, process, or* purpose.	1. Use a checklist to verify *critical material properties at* source. 2. Make defective material unusable or obvious as soon as discovered. 3. *For materials that may degrade or fail during* processing: • Provide continuous performance monitoring. • Check condition at regular intervals.

ANNEXE 5 Examples of non-conformances and preventions (Step 4)

Case 1 [2]

Problem	: Plastic covers scratched when screw-driver slipped out of screw head.
Process	: Mounting cassette covers.
Part/Component	: Screws.
Information	:
Solution	: Change shape of screw head

Description of process: Plastic cassette covers assembled with screws.

Before mistake-proofing	After mistake -proofing
Cassette covers frequently scratched when screwdriver slipped out of screw head and slid out against plastic covers.	Change made to shape of screw head to prevent screwdriver from slipping. Scratches caused by screwdriver completely eliminated.
	

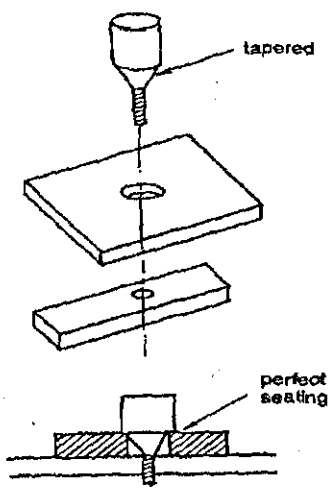
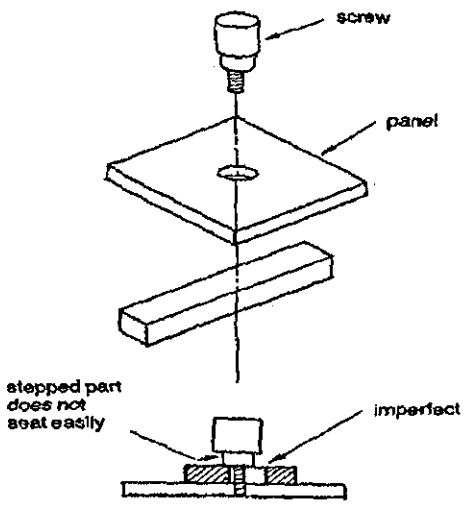
Source: Nikkan Kogyo Shimbun (1988), Hinckley (2001).

ANNEXE 5 (continued)

Case 2 [2]

Problem	: Decorative screws difficult to seat properly.
Process	: Fixing decorative screws.
Part/Component	: Decorative screws.
Information	:
Solution	: Change type of screw.

Description of process: Decorative screws fixed on workpieces.

Before mistake-proofing	After mistake -proofing
Screws difficult to seat properly. Misaligned screws could be discovered only during packing, at which time it was necessary to loosen and tighten screw repeatedly to get it to seat properly. Process became bottleneck on assembly line.	Shape of screw changed. Stepped part on screw was changed to tapered. Now possible to tighten screw right into hole in one operation.
	

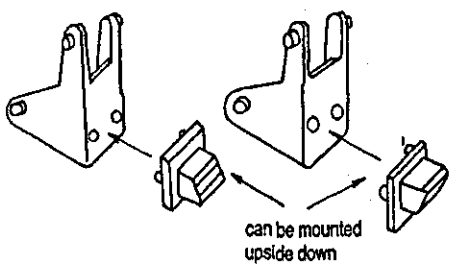
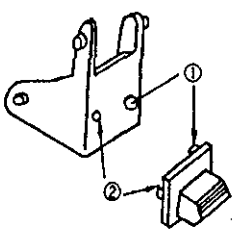
Source: Nikkan Kogyo Shimbun (1988), Hinckley (2001).

ANNEXE 5 (continue)

Case 3 [2]

Problem	: Eject buttons mounted upside down.
Process	: Mounting cassette deck buttons.
Part/Component	: Cassette buttons.
Information	:
Solution	: Make mounting pins different diameters.

Description of process: Cassette deck eject buttons mounted onto control arms.

Before mistake-proofing	After mistake -proofing
Eject buttons could be mounted in either direction, sometimes mounted upside down.	Diameters of mounting pins made unequal. Upside down mounting impossible and faulty mounting completely eliminated.
	

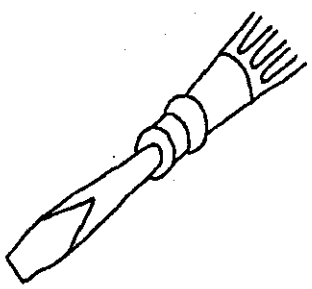
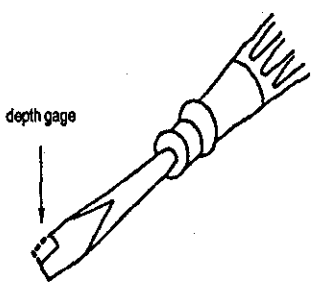
Source: Nikkan Kogyo Shimbun (1988).

ANNEXE 5 (continue)

Case 4 [2]

Problem	: Spring mounted to incorrect depth.
Process	: Mounting battery springs.
Part/Component	: Spring, screwdriver.
Information	:
Solution	: *Improve mounting tool to measure depth.*

Description of process: Battery springs mounted into portable electronic products.

Before mistake-proofing	After mistake -proofing
Ordinary screwdriver used to push springs into holes, and proper positioning depended on skill of workers. However, defects because springs could be pushed down below their positions.	Tip of screwdriver cut as shown so it acts as stopper or depth gauge. Anyone performing operation now can push springs to proper position with no trouble. Defects completely eliminated.
 ordinary screwdriver	 "improved" screwdriver

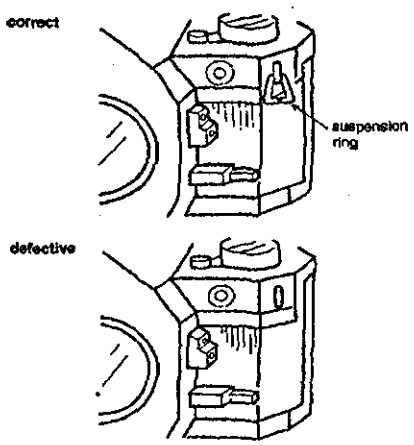
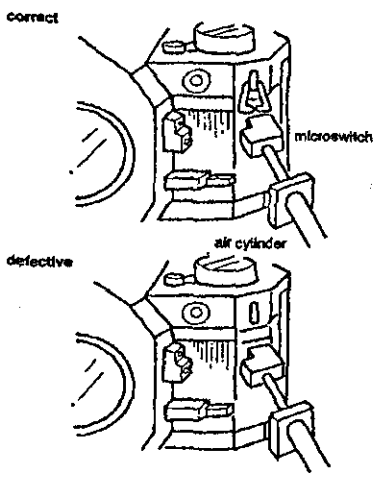
Source: Nikkan Kogyo Shimbun (1988).

ANNEXE 5 (continue)

Case 5 [2]

Problem	: Missing camera strap rings.
Process	: Camera case assembly.
Part/Component	: Strap rings
Information	:
Solution	: Microswitch and air cylinder automatically detect missing rings before final inspection.

Description of process: Rings for camera straps mounted at one point in camera assembly process.

Before mistake-proofing	After mistake -proofing
Since suspension rings have no effect on functions of camera, possible to be neglect. Visual checking errors sometimes occurred and omission often not discovered until final inspection of camera's external features.	Visual check for rings replaced by using micro-switch and air cylinder. Checking device mounted on inspection table and detection performed automatically as part of inspection procedure.
	

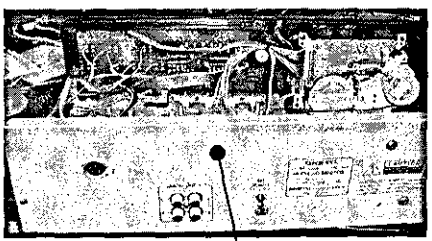
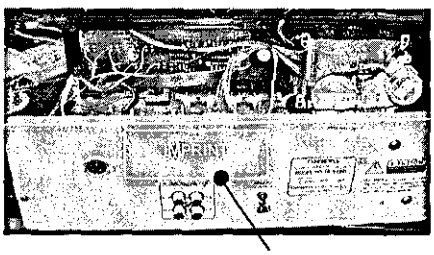
Source: Nikkan Kogyo Shimbun (1988).

ANNEXE 5 (continued)

Case 6

Problem	: Missing safety labels
Process	: Sticking safety labels
Part/Component	: Safety labels
Information	: Safety standards/requirements
Solution	: Imprint marker for safety labels

Description of process: Safety labels pasted on rear panel in final assembly process.

Before mistake-proofing	After mistake -proofing
Safety labels sometimes omitted especially, when changing product versions. Labels also pasted inconsistently, as work instruction did not specify accurately.	For different products using same parts, imprint square line for safety labels. Working instruction informed clearly which version needed safely label, and position of label is fixed.
 Missing label	 Label box imprinted on back panel

APPENDIX C: PHASE 1 EVALUATION

C1. Schedule of Questions to Evaluate New Approaches

EXPERT PANEL INTERVIEW

SCHEDULE OF QUESTIONS

(Phase 1)

GENERAL INSTRUCTIONS AND INTERVIEWER SELF-INTRODUCTION

First of all, I would like to thank you, Mr/Mrs/Ms. _____, for allowing me to carry out this interview, which is also known as an **expert panel interview**. The purpose of this interview is quite self-explanatory, that is to get an **expert evaluation,** from a person like you, on **specific aspects** related to my research, as well as the industry, as a whole. Your answers are very important to the accuracy of the research, and I can assure you that they will be treated and kept as **strictly confidential**.

Before we begin, Mr._____, allow me to introduce myself. My name is Roslan Jamaludin. I am currently pursuing a 3-year PhD research programme at the Wolfson School of Mechanical & Manufacturing Engineering, Loughborough University, UK, since December 2003. I am a Product Designer by qualification, and teaching Production Technology in Universiti Utara Malaysia. My research focuses on **Identifying and Controlling Product Non-conformances in Pre-production.**

For effective discussion, ***this interview will be divided into* 4 parts,** such that the subjects can be addressed appropriately.

PART A – Expert and Company Profile
PART B – General Questions on Pre-production, Validation and Non-Conformances
PART C – Expert Evaluation on New Approaches
CONCLUSION

(Note: The following questions require PERCEPTION, CRITICISM, COMMENT AND SUGGESTION about the new approaches).

PART A – Expert and Company Profile

Expert and Company Profiles

Q A1: For the record, could you please state your **personal details,**

- What is your **designation**?
- How many years and months in your present **position**?
- How many **years' experience** with this company?

Q A2: Could you please give a brief **description of your company's**

- business **profile** and **products**?
- **head office** location?

Q A3: What is company current **business philosophy** on product and quality?

End of PART A

PART B – General Questions on Pre-production, Validation Process and Non-Conformances

Pre-production

Q B1: To which department is pre-production **accountable,** e.g. R&D or Production?

Q B2: Briefly, how is pre-production **operating**?

Q B3: What is the **interaction** between pre-production with other functions within the company, and in what capacity?

Q B4: In the context of an assembly plant being **geographically distant** from head office, can you explain the day-to-day operation of pre-production in this situation?

Q B5: Do you agree that the pre-production function has **sufficient capabilities** and **experiences** to identify and control product non-conformances? If no, what can be done?

Q B6: In your view, do you agree that product varieties, volume and planning have **significant implication** for pre-production? Are there any other factors?

(continued)

PART B (continued)

Validation Process

Q B7: What can you say about **product validation,** i.e. how validation is normally conducted?

Q B8: What **aspects** do you consider in validation, i.e. main aspects that are **significant** or **given priority**?

Q B9: What **tools or approaches** are commonly used to validate products, and to ease validation tasks?

Q B10: How do you **measure** the validation outcomes?

Q B11: What is your opinion that *'validation is just to check product conformances to specifications'*? Is there any **other purpose**?

(continued)

PART B (continued)

Product Non-conformances

Q B12: How do you **define non-conformances** in product validation, and could you describe products that are non-conforming, with examples?

Q B13: Can you suggest ways to **identify** and **control** non-conformances in pre-production.

Q B14: Who is involved in resolving these non-conformances, i.e. are other functions involved in solving non-conformances?

End of PART B

PART C – Evaluating Concept of Identification and Control of Product Non-Conformances in Pre-Production

The purpose of this evaluation is to get expert opinion and response on the proposed **new approaches for validating products**. The aim of the approaches is to identify and control product **non-conformances** as the consequence of *mistakes*. There are three components that make-up the approaches:

- validation process
- concepts of identification and control of non-conformances
- tools and techniques

The approaches introduce three concepts, as follows:

- product characteristics and validation consideration: **Information, Process** and **Parts/Components**.
- product non-conformance classification, known as **Product-based Non-conformances Classification, or PNC.**
- product non-conformance rapid control technique, known as **Non-conformance Consequences and Solutions, or NoCoS, methodology.**

(Please mark the appropriate response, and if necessary, elaborate. Explanations on the new approaches will be provided, where necessary).

Q C1. Product Validation Model

Would you suggest that the **product validation model**, as shown below, is

	Yes	No	Not Sure	Don't Know	Please elaborate
i. relevant in pre-production?					
ii. practical?					

Brief:

The validation model, as shown in Figure 1, consists of:

- **INPUT**, complete set of product and accompanying documentation.
- **OUTPUT**, product and accompanying documents either in conformance or non-conforming.
- **CONTROL**, validation considerations – Information, Process and Parts/Components
- **MECHANISM**, inspection as the means of validation.
- **PROCESS**, conduct of validation.

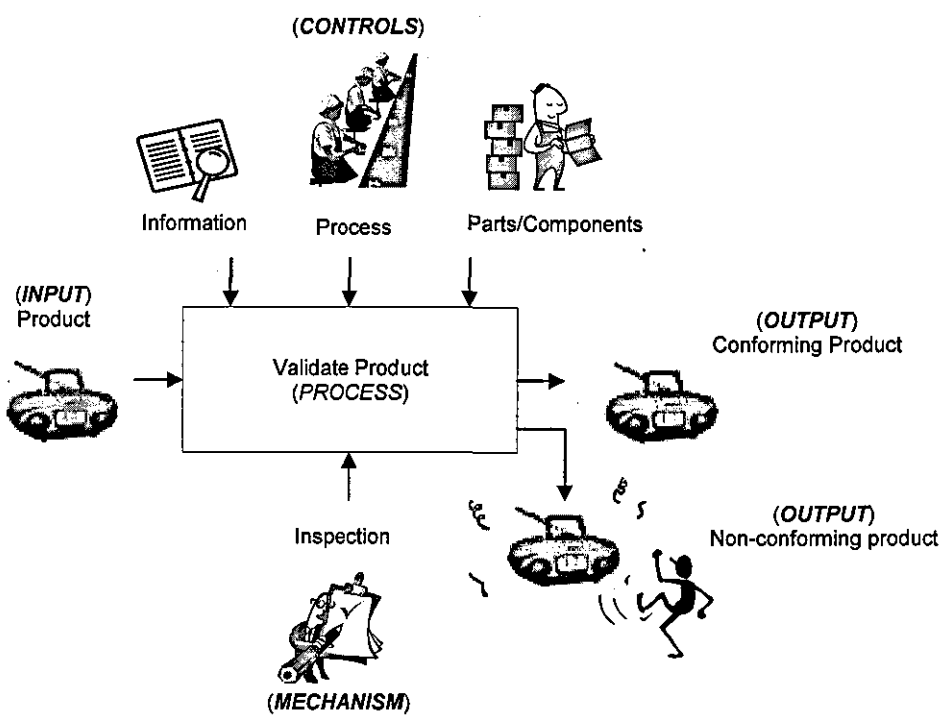


Figure 1 Product validation model

Q C2. Product Validation Process

Is the **validation process** as structured below,

	Yes	No	Not Sure	Don't Know	Please elaborate
i. covering all major process of validation?					
ii. relevant in pre-production?					
iii. coherent?					
iv. practical?					

Brief:

There are five steps in the validation process, as shown in Figure 2:

- **Step1 INITIATION,** preparing the product and inspection teams,
- **Step2 DETECTION,** identifying non-conformances on product and trial-run based on Product-based Non-conformance Classification/PNC (described in the following sections),
- **Step 3 ANALYSIS,** determining non-conformances based on Non-conformances Consequences and Solutions (NoCoS) methodology (described in the following sections),
- **Step 4 RECTIFICATION,** deploying solutions and preventions of non-conformances,
- **Step 5 VERIFICATION,** confirmation that inspection and rectification of non-conformances have been completed.

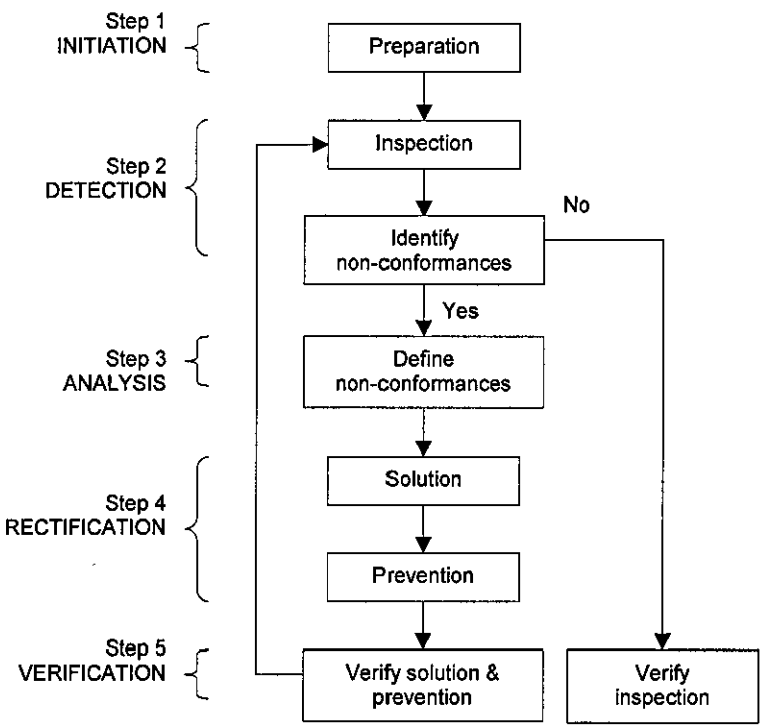


Figure 2 Product validation process flow chart

Q C3. Product Characteristics

Are the **key characteristics** of the product under validation, as shown below

	Yes	No	Not Sure	Don't Know	Please elaborate
i. relevant to validation?					
ii. coherent?					
iii. comprehensive?					

Brief:

The product under validation consists of three interrelated characteristics, as shown in Figure 3:

- **INFORMATION**
- **PROCESS**
- **PARTS/COMPONENTS**

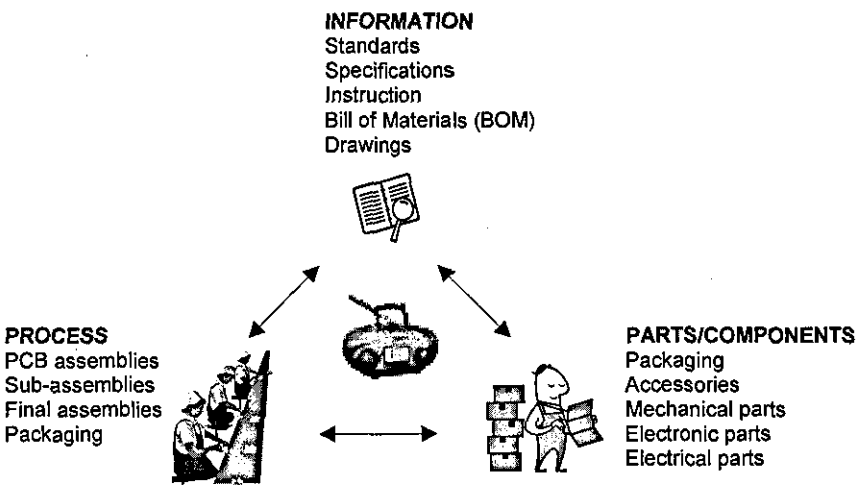


Figure 3 Interrelated product characteristics

Q C4. Product-Based Non-Conformance Classification, or PNC

In your opinion, are the classes of non-conformances (PNC) related to mistakes, shown below,

	Yes	No	Not Sure	Don't Know	Please elaborate
i. relevant in identifying product non-conformances?					
ii. covering most non-conformances?					
iii. coherent?					
iv. practical?					

Brief:

As shown in Figure 4a, three product characteristics are related to mistakes, in which non-conformances are classified into:

- **INFORMATION NON-CONFORMANCES**
- **PROCESS NON-CONFORMANCES**
- **PARTS/COMPONENTS NON-CONFORMANCES**

Table 4a shows the classes of non-conformances related to mistakes.

Figure 4b shows examples of manifestation of mistakes during validation on product safety.

Tables 4b and 4c show the connection between mistakes and non-conforming items.

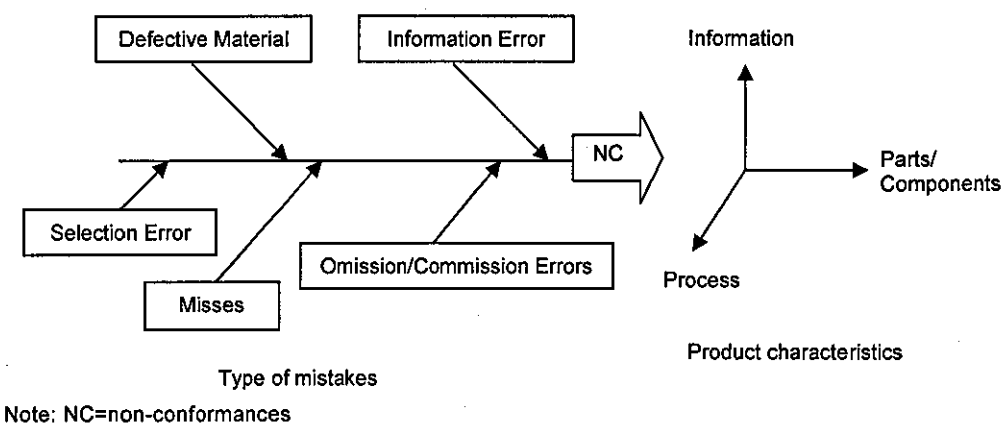


Figure 4a Relationship between product characteristics and mistakes.

(continued)

Q C4. (continued)

Table 4a Classes of non-conformance and description of mistakes.

Class of non-conformance	Locality of non-conformances	*Mistakes*	*Description of mistakes*
INFORMATION	Technical specifications Work instructions Bill-of-materials Drawings Checklist Engineering change order	Ambiguous Information	Information can be interpreted in many ways, and some interpretations may be incorrect.
		Incorrect Information	Information provided is incorrect.
		Misread, Mis-Measure, Misinterpret	Gauge-reading errors, errors in measuring, or errors in understanding correct information.
PROCESS	PCB assemblies Sub-assemblies Final assemblies Packaging	Omitted Operations	Failure to perform a required *operation.*
		Wrong Part	Part is selected, but it is the wrong part.
		Wrong Orientation	Part is inserted in the correct location, but the part has wrong orientation.
		Wrong Operation	An operation is executed, but wrong operation is used.
		Wrong Location	Part insertion or process execution in an incorrect location which is not the result of incorrectly orienting parts.
		Wrong Destination	After completing an operation, product is sent to the wrong address or destination.
PARTS/ COMPONENTS	Packaging materials Accessories Mechanical parts Electronic parts Electrical parts	Defective Materials	Material *entering* a process is defective, or inadequate for the intended function, process, or purpose.

(continued)

Q C4. (continued)

Class of Non-conformances			*Parts/ Components*	*Information*					*Process*												
Particular	Part	Item	Defective material entering	Ambiguous information	Incorrect information	Mismeasurement	Omitted information	Inadequate warning	Misaligned parts	Misadjustment	Added material or part	Prohibited act	Omitted operations	Omitted part	Counting errors	Wrong material	Wrong destination	Wrong location	Wrong operation	Wrong part	Wrong orientation
Safety	Label	Carton box			◉		◉	◉													
		Plastic wrapper			◉		◉	◉													
		Rear panel			◉		◉	◉													
	Electrical	Power cord	◉	○				○								◉				◉	○
		Wire harness	◉						◉		◉			◉		◉	○	○	○	◉	◉
		Cord clamp	◉							○				◉		◉		○		◉	◉
		Tie band	◉						◉	○	◉	○	◉	◉	○	◉	○	◉	◉	◉	◉

Legend
◉ high probability ○ low probability

Figure 4b Examples of mistakes and non-conformances related to product safety

(continued)

Q C4. (continued)

Table 4c Connections between mistakes and classes of non-conformances.

⊙ Strong Connection
O Connection
Blank Weak/No Connection

		P/C	Information					Process												
		Defective material	Ambiguous	Incorrect	Mismeasure, interpret	Omitted Information	Inadequate Warning	Misalign	Misadjust	Mistimed or Rushed	Added Parts	Prohibited act	Omitted Operation	Omitted Parts	Concept or Material	Destination error	Location error	Operation error	Parts error	Orientation error
P/C	Defective Material							O	⊙	⊙		O	⊙	⊙				⊙	⊙	⊙
Information	Ambiguous				⊙			⊙	⊙				O				O	⊙	⊙	O
	Incorrect				⊙				⊙	⊙		⊙			O	⊙		⊙		
	Mismeasure, interpret	O	⊙	O				⊙	⊙	⊙					⊙		O			O
	Omitted Information							O	O			⊙	O	O	⊙		O	O	O	
	Inadequate Warning							⊙	⊙	⊙										
Process	Misalign	O	⊙		⊙	O	⊙		⊙	⊙			O	O			⊙			⊙
	Misadjust	⊙	⊙	⊙	⊙	O	⊙	⊙		⊙		O					O			O
	Mistimed or Rushed	⊙		⊙	⊙		⊙	⊙	⊙			O	⊙	⊙		O	O	O	O	O
	Added Parts											⊙		O					O	
	Commit Prohibited	O		⊙		⊙			O	O	⊙				O					
	Omitted Operation	⊙	O			O		O		⊙				⊙	⊙			⊙		
	Omitted Parts	⊙				O		O		⊙	O		⊙				O	O	O	
	Concept or Material			O	⊙	⊙						O	⊙					⊙	⊙	
	Destination			⊙						O							⊙		⊙	
	Location		O		O	O		⊙	O	O				O		⊙		O	O	⊙
	Operation	⊙	⊙	⊙		O				O			⊙	O	⊙		O		⊙	⊙
	Parts	⊙	⊙			O				O	O			O	O	O	O	O		O
	Orientation	⊙	O		O	O		⊙	O	O							⊙	⊙	O	

Q C5. Non-Conformance Consequence and Solution Methodology

Do you think that controlling non-conformances based on the **consequences and solutions (NoCoS)**, as described below, is

	Yes	No	Not Sure	Don't Know	Please elaborate
i. relevant in controlling non-conformances?					
ii. covering all major consequences and solutions of non-conformances?					
iii. coherent?					
iv. practical?					

Brief:

Non-conformances Consequence/Solution – NoCoS methodology is used to control non-conformances. The methodology involves two processes:

1. Non-conformances are determined according to Consequence Level and Solution Status, shown in Table 5a.

Table 5a Coding and description of NoCoS methodology

	Coding/description
Consequence Level	**C1 :** non-conformance with **safety** standard and requirement. **C2 :** non-conformance that results in product **not producible**. **C3:** non-conformance that results in product that can be produced but with big problems, or will not be accepted by **critical** customer. **C4 :** non-conformance that results in product that can be sold or produced with **minor** difficulties. **C5 :** non-conformance **accepted** by management – no activities will be started to reduce or eliminate this problem
Solution Status	**S1** : solution not known **S2** : solution known but not yet positive **S3** : solution known but not yet introduced **S4** : solution known and introduced

2. Identified non-conformances are logged into the **NoCoS matrix,** as shown in Table 5b, while Table 5c shows a simulated matrix with transmitted non-conformances data. Figure 5 shows accumulated data which represent non-conformances condition of product under validation to be scrutinised appropriately.

Table 5b NoCoS matrix

		Non-conformance Consequence Level				
		C1	C2	C3	C4	C5
Solution Status	S1					
	S2					
	S3					
	S4					

Table 5c Simulated NoCoS matrix

		Non-conformance Consequence Level				
		C1	C2	C3	C4	C5
Solution Status	S1	15	4	2	3	13
	S2	10	2	17	2	7
	S3	5	2	3	1	1
	S4	10	6	2	2	12

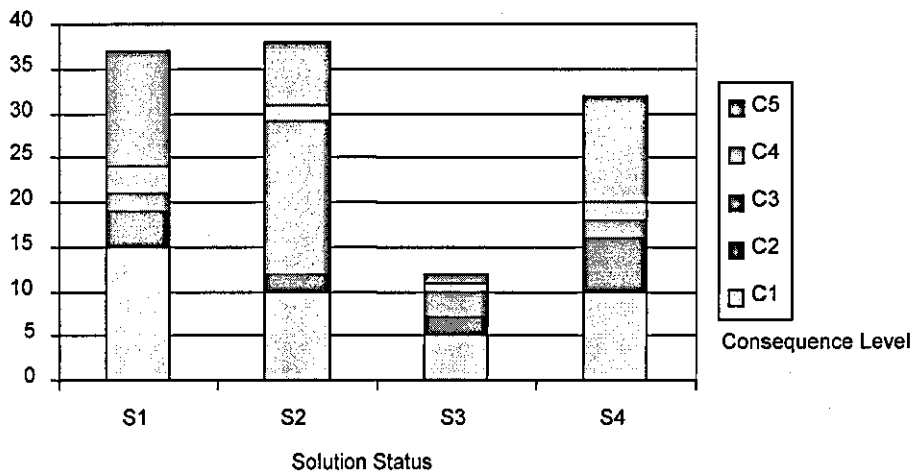


Figure 5 Simulated results of accumulated non-conformances.

Q C6. Preventing Non-Conformances by Mistake-Proofing

Is mistake-proofing technique, as described below,	Yes	No	Not Sure	Don't Know	Please elaborate
i. relevant in rectifying non-conformances in pre-production?					
ii. a sensible approach?					
iii. practical?					

Brief:

Mistake-proofing technique is adopted as a prevention approach to prevent non-conformances, as described in Figure 6.

Examples of mistakes and **prevention by mistake-proofing techniques,** according to PNC, are provided in Table 6.

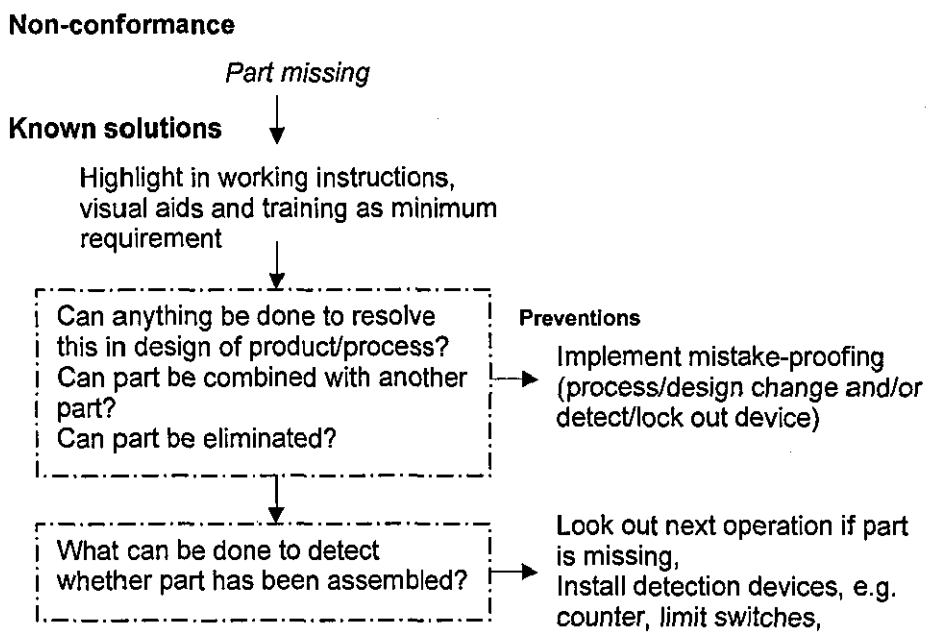


Figure 6 Deploying solutions and preventions

(continued)

Q C6. (continued)

Table 6 List of mistakes and mistake-proofing techniques

Information non-conformances

NC	Description	MISTAKE-PROOFING TECHNIQUES
AMBIGUOUS INFORMATION	Information can be interpreted many ways, some interpretations may be incorrect.	1. Where possible, simplify task, instruction, or specification. • Minimise number and similarity of parts and tools. • Identify and remove unnecessary material using red tags/marks. • Minimise number and complexity of operations. • Make instruction brief and graphic. • Minimise or eliminate need to add up dimensions and tolerances to fabricate parts. 2. Make labels, messages, instructions, and controls easy to see, read, and reach. 3. Limit amount of information available. 4. Make various types of information distinctly different. • Visual-group related items and distinguish by colour. 5. Use pictures, videos, graphics, or drawings to identify complex parts and clarify complex operations.
INCORRECT INFORMATION	Information provided incorrect.	1. Prevent spurious information. 2. Ensure that instructions cannot be skipped or repeated. 3. Use checklist to verify that results match predictions or requirements. 4. Review instructions and information for accuracy. 5. Have several individuals with diverse backgrounds review instructions and specifications to identify and eliminate potential ambiguity. 6. Look-alike parts must have drawing numbers that differ.
MISREAD, MISMEASURE, OR MISINTERPRET	Errors in gauge-reading, measuring, or in understanding correct information.	1. Make interpretation easy: • Drawings, pictures, or videos illustrate complex parts, concepts, or operations. 2. Print required dimension guide on worksheet.

Parts/Components non-conformances

NC	Example	MISTAKE-PROOFING APPROACH
DEFECTIVE MATERIALS	Material *entering* a process defective, or inadequate for intended function, process, or purpose.	1. Use checklist to verify critical material properties at source. 2. Make defective material unusable or obvious as soon as discovered. 3. For materials that may degrade or fail during processing: • Provide continuous performance monitoring. • Check condition at regular intervals.

(continued)

Table 6 (continued)

Table 6 List of mistakes and mistake-proofing techniques

Process non-conformances

NC	Example	MISTAKE-PROOFING APPROACH
OMITTED PARTS AND COUNTING ERRORS	Missing part or wrong number of parts resulting from counting error.	1. Eliminate parts by combining functions with other parts. 2. Make part omission errors and counting errors obvious. 3. Layout makes missing parts obvious (remainder method). 4. Prevent an operation if part missing.
OMITTED OPERATIONS	Failure to perform required operation.	1. Prepare standard procedure charts. 2. Create and use operation checklist. 3. Eliminate need for operation, e.g. by simplifying product or process. 4. Make omitted operations visible and obvious, e.g. detect omission of operation by comparison to correctly completed items
WRONG PART	Part selected, but wrong part.	1. Change design so that same part can be used in right- and left-hand locations. 2. Look-alike parts at each work station minimised, eliminated, or non-interchangeable. 3. Interference prevents assembly of similar but wrong part. 4. Identical parts made of dissimilar material clearly marked.
WRONG ORIENTATION	Part inserted in correct location, but part has wrong orientation.	1. Where possible, make parts symmetrical, e.g. end-to-end symmetry. 2. Make parts asymmetric, and make asymmetry obvious (shape/dimension), 3. Interference prevents set-up or assembly of asymmetrical parts in wrong orientation.
WRONG OPERATION	Operation executed, but wrong operation used.	1. Mistake-proof selection of instructions, have only one instruction visible at a time. 2. Single design used for both right and left hand parts. 3. Redesign, making control setting easy to read. 4. Standard procedure chart guides selection of correct operation.
WRONG LOCATION	Part insertion or process execution in incorrect location not result of incorrectly oriented parts.	1. Simplify design to eliminate inserting (retrieving) parts or materials in wrong location. 2. Change design so that one part fits all locations. 3. Reduce types of fasteners. 4. Interference prevents insertion in wrong location (shape or dimensions). 5. Asymmetrical pin and hole pattern allows only one location. 6. Variety of parts, each has unique shape and mating insertion feature. 7. Interference detects defect.
WRONG DESTINATION	After completing operation, product sent to wrong address or destination	1. Keep destination information linked with product.
WRONG CONCEPT	Design-decision errors resulting in incompatible materials, hazardous products, non-functional products, or any one of wide range of problems. Such errors can also result in products subject to excessive wear, not robust, unreliable, or unsatisfactory to customers.	1. Develop and maintain design checklists unique to specific products. 2. Button and switch locations easy to see, and labels easy to read 3. Parts have adequate constraints 4. Parts accessible for disassembly and maintenance

Q C7. Overall Methodology

In your opinion, after evaluating the new approaches in product validation process, do you suggest the approaches is

	Yes	No	Not Sure	Don't Know	Please elaborate
i coherent?					
ii. practical?					
iii. recommended?					

End of PART C

CONCLUSION

Q1: In conclusion, based on matters that you have mentioned or discussed on product quality, pre-production and validation processes, which specific areas or issues do you believe should be given the **most attention** as far as studies/research on product quality in Product Development Process is concerned?

Q2: Would you like to **make any other comments** about the concepts we have discussed during the interview?

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Thank you, Mr._____ for your time and willingness to participate in this evaluation session. Your opinion and views will definitely be used and referred to throughout this research. With your permission, I would be grateful if you would be willing to be interviewed again, if necessary, at any time during the research.

Thank you, and that will be the end of the interview.

APPENDIX C: PHASE 1 EVALUATION

C2. Phase 1 Evaluation: Results and Interview Transcription

TRANSCRIPTION

(Phase 1)

Q C1. Product Validation Model

Would you suggest that the **product validation model**, as shown below, is

	Yes	No	Not Sure	Don't Know	Please elaborate
i. relevant in pre-production?					
ii. practical?					

Evaluators' responses:

Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i. relevant in pre-production?	Yes	Yes	Yes	Yes	Yes	Yes
ii. practical?	Yes	No	Yes	Yes	Yes	Yes
	2 items/12 responses (Yes= 11, No = 1)					

Evaluators' comments:

Evaluator A:

"First of all, we do not call it product under validation, we called it 'programme' or 'sample' while at the development stage. On the model, basically, it is similar to what we are doing. We have a few stages:

F – Feasibility, the first engineering sample tested as totally new product not leveraged, requires new process, tools, do trial and error, machine set-up, build small volume for validation. Then review design, process, material, and functionality. This is where a lot of non-conformances were captured and changes took place.

D – Development, after meeting the F-built criteria, then moves to D – built criteria using working Plan of Record (POR) process. For volume capability against POR component, POR process, and POR materials. Leverage product undergoes this stage. Full test and check reliability, functionality, quality, process, mechanical, etc.

V – Validation, demonstrate high volume capability, for example dppm level, batch, etc. (ramp-up - a), then release for volume. So there should be smaller boxes inside the big one to represents the stages.

The model, therefore, is definitely relevant and workable since most of it we applied, but the way we execute may be different. On the controls, that specification or requirement is vague. I agree validation not on product but also on process, tools, etc., especially new products, but leverage products differently where there is no change in tool and process".

Evaluator B:

"My thinking is this is a one-stop condition where you do everything in one stage. You need to have some loose condition where we cannot change from prototype to final product in one big push. You need to segregate in detail each inspection because ideally it looks like this one but the different people need to have different conditions. You have to divide it into several categories".

Evaluator C:

"Yes, it is very much feasible and practical. To my understanding, inspecting and testing is validation. The outcome of validation is 'yes' or 'no'. Basically, this model is correct from a prototype point of view, and very much relevant".

Evaluator D:

"This is a picture of overall prototype validation until finished product. These are the elements in validation (the mechanism and controls – a). Generally it's ok, correct, feasible and relevant".

Evaluator E:

"Almost the same, from the first stage to the final product. It is relevant".

Evaluator F:

"I suggest adding simulation and survey to the mechanism, and customer's view on quality to information. The run-rate certification, i.e. the prototypes built and validation involving variation such as different lines, timing, random batch, different lot of material from suppliers, to replicate the real production condition and capture variation. We have thousands of parts variation from suppliers. I'd say it's relevant and practical".

Q C2. Prototype Validation Process

Is the ***validation process*** as structured below,

	Yes	No	Not Sure	Don't Know	Please elaborate
i. covering all major process of validation?					
ii. relevant in pre-production?					
iii. coherent?					
iv. practical?					

Evaluators' responses:

Evaluator	A	*B*	*C*	*D*	*E*	*F*
i. covering all major process of validation?	Yes	Yes	Yes	Yes	Yes	Yes
ii. relevant in pre-production?	Yes	Yes	Yes	Yes	Yes	Yes
iii. coherent?	Yes	Yes	Yes	Yes	Yes	Yes
iv. practical?	No	Yes	Yes	Yes	Yes	Yes

4 items/24 responses (Yes= 23, No= 1)

Evaluators' comments:

Evaluator A:

"Validation is on engineering sample during pilot run, pilot built in small volume products. On the engineering aspects – process, tool, cycle time, etc. then the pilot samples sent for inspection and testing with the software, mechanical conformances, changes, chemical test, noise test, etc. Some non-conformances may not be captured at the early stage, but at later stages.

Analysis will look on how to 'fix' any non-conformance. For known fix, we will recover immediately, then re-inspect the product. For unknown fix, further analysis is conducted until solution is found, then reiterate the validation. This flow is correct, relevant, comprehensive and practical, but not sure it's coherent because some aspects may not included".

Evaluator B:

"I can agree on this, but I have one question, what is the limit of the non-conformance? Sometimes it is out of specification, but which specification are

we talking about and is there any special acceptance for it? There are several types of non-conformance, i.e. the quality bottom where it is severe when it fails to conform with quality requirement, need to come out with excuses to defend when specification could not be met, especially involving safety and health".

Evaluator C:

"As we develop and assemble here, we don't do prototype breakdown to validate. In the first stage, we validate prototypes samples, less than 200 units, by R&D and Engineering. Second stage we produce and validate pre-production samples between 200 to 1000 units by Process Engineering. In between the stages, if non-conformance is discovered, corrections and changes are made, then trial-runs are conducted as the PDCA loop or cycle.

On the analysis, recovery and prevention need to reiterate the validation process after every time there are changes and correction. It covers all, relevant, coherent, ease of implementation, but a bit very general".

Evaluator D:

"The first one is engineering sample, to evaluate for example parts from suppliers. The second one is not a prototype; we called it a tooling sample, still during pre-production. This is relevant and applicable, suitable for describing the process for training purposes".

Evaluator E:

"Almost the same, from the first stage to the final product. We did break it down looking for example new components and unusual process to mount; if it needs a special process to mount we'll highlight it. We were given around two or three sets to do this. We used this as reference for trial run.

After validation, if there's any improvement, correction and countermeasure, we'll revalidate. Other activities are similar. They are sensible, uncomplicated, comprehensive and relevant".

Evaluator F:

"Reiterate the validation on the 'damage done product' after correction, until no more possible non-conformances. R&D will fix and make good the non-conformance and the NPI validate again. Consider also time, as we validate at different variations, conditions and stages to replicate and get the same result. It is relevant and covers major aspects".

Q C3. Product Characteristics

Are the **key characteristics** of the product under validation, as shown below

	Yes	No	Not Sure	Don't Know	Please elaborate
i. relevant to validation?					
ii. coherent?					
iii. comprehensive?					

Evaluators' responses:

Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i. relevant to validation?	Yes	Yes	Yes	Yes	Yes	Yes
ii. coherent?	Yes	Yes	Yes	Yes	Yes	No
iii. comprehensive?	Yes	Yes	Yes	Yes	Yes	Yes

3 items/18 responses (17 = Yes, 1 = No)

Evaluators' comments:

Evaluator A:

"You need to include software and firmware i.e. the source codes, into the information since this will translate what the customer's requirements are. The process shown is similar, while on the parts/components we have are two, i.e. the hard disk assembly or mechanical parts, and PCB assembly or electronic parts. The product characteristics cover major aspects in prototype, relevant, coherent and comprehensive".

Evaluator B:

"This one they say as - see the actual part, see the drawing and see the part number. This is the three-way. We make a triangle – actual part, drawings and part identification. I like this one, as I see it, to make a product; we need to conform to several aspects, with this triangle".

Evaluator C:

"The product characteristics, information is correct, process is fine, and parts/components are also fine. Include also things like legal, standards, and certification, since now there are a lot of requirements by various standards institutions".

Evaluator D:

"This is correct for internal validation. It's very relevant to us".

Evaluator E:

"In the production, too, these are the components; hence they are relevant, coherent and comprehensive".

Evaluator F:

"It is relevant and logical, but does not consider timing, like testing the reliability over time"

Q C4. Product-Based Non-Conformance Classification (PNC)

In your opinion, are the classes of non-conformances (PNC) related to mistakes, shown below,

	Yes	No	Not Sure	Don't Know	Please elaborate
i. relevant in identifying product non-conformances?					
ii. covering most non-conformances?					
iii. coherent?					
iv. practical?					

Evaluators' response:

Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i. relevant in identifying non-conformances?	Yes	Yes	Yes	Yes	Yes	Yes
ii. covering most non-conformances?	Yes	Yes	Yes	Yes	Yes	Yes
iii. coherent?	Yes	Yes	Yes	Yes	Yes	Yes
iv. practical?	Yes	Yes	Yes	Yes	Yes	Yes
						4 items/24 responses (24 = Yes)

Evaluators' response:

Evaluator A:

"As to what was being discussed earlier, this is relevant. Most of the non-conformances are *human error* (like 70 %), for example when a product was assembled here without problems, but when assembled elsewhere we faced problems, non-conformances in the process.

Others like assumptions which led to for example misses, different specifications for different stages are not matching, wrong information, etc.

Your classification could be used to generalise Hinckley's classification since his is too many. Hence, this diagram covers all aspect, relevant in capturing non-conformances, coherent, and uncomplicated. I think this is *categorically correct* in defining non-conformances".

Evaluator B:

"These are normally process non-conformances and quite general. We have to classify into several pieces of time, for example reliability test. In our company, we have three booklets – the reliability standard, general product standard, and general conformance standard.

Need to include *training* to make operators, suppliers and inspectors competence for inspection to identify the No Good point.

So far I can understand this idea. This is good, one of the QC tools (the fishbone); and this is also good, I can agree with this, used for prototype (the correlation table of non-conformances)".

Evaluator C:

"Actually, when I go through this kind approach, it *wakes me up,* because when we do or develop things we always tend to have a biased feeling that what we do is perfect, we ignored the non-conformances.

In order to make the product successful we must put the effort on non-conformances. We have to find whatever possible non-conformances. In development, we have to look at non-conformances. Inspection is to find non-conformances. It's been human nature to ignore or take lightly the non-conformances. That's a mistake.

I see these as non-conformances as *risk management.* I think we should focus on non-conformances rather then the success of the performance because, for example 700 items to inspect, when 680 passed and 20 failed, we should not be happy. It should be 700 of 700 passes i.e. zero defect, then we can proceed to mass production. However, during pre-production we are allowed to make mistakes, like 7% of non-conformances due to manufacturing or whatever, but not due to design. At this stage (pre-production) non-conformances from design should be zero. So I think this is correct, covers major aspects, relevant, coherent, uncomplicated, and practical".

Evaluator D:

"Yes, I agree with categorisation – design, process or parts. The non-conformances are very much relevant".

Evaluator E:

"I agree that the components are correct and the relationship is correct. This provides the *broader view and clear picture of non-conformances* and the correlations between specific non-conformances".

Evaluator F:

"I look more at for example parts and components due to *variation and capabilities* instead of the causes, while management view looks at cost savings. But I do agree with these particulars".

Q C5. Non-conformance Consequences/Solutions (NoCoS) methodology

Do you think that controlling non-conformances based on the **consequences and solutions (NoCoS)**, as described below, is

	Yes	No	Not Sure	Don't Know	Please elaborate
i. relevant in controlling non-conformances?					
ii. covering all major consequences and solutions of non-conformances?					
iii. coherent?					
iv. practical?					

Evaluators' response:

Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i. relevant in controlling non-conformances?	Yes	Yes	Yes	Yes	Yes	Yes
ii. covering all major consequences and solutions of non-conformances?	Yes	Yes	Yes	Yes	Yes	Yes
iii. coherent?	No	Yes	Yes	Yes	Yes	Yes
iv. practical ?	Not sure	Yes	Yes	Yes	Yes	Yes
	4 items/24 responses (22 = Yes, 1 = No, 1 = Not sure)					

Evaluators' response:

Evaluator A:

> "We uses colour coding to define non-conformances based on yield of defect parts per million or dppm, or failure rate, for example green if less than 0.5%, and does not affect quality and customer; yellow 0.5 – 1.0%, not critical but have to fix it; red > 1.0% critical, review and make decision whether to stop or not whatever the situation, and bring down to green.
>
> Looking at this table and your explanation, it can be used as one way. It's good and appropriate since it describes the consequence or the impact of the problem. However, to conduct the analysis, training is required to be competent in using this matrix or for maybe work in a new company. The table is flexible, but not

sure whether it is practical or uncomplicated; need to prove or test it in practical environment".

Evaluator B:

"This is an academic work, you can generate as much the result or outcome, but at the end of the day is the judgement whether the product complies of not. Not about the solution. Because sometimes it is hard to get the solution in that time, so need to stop the line, but if go - conditionally, line proceeds.

Looking at this matrix, I can agree with these, it shows some kind of key issues here. You really classify into what is Critical to Quality or CTQ. These we interpreted whether the customer is satisfied with the product with our specification and condition, and how the customer receives the product, since we are giving more than they requires. However, on the item, not producible is too broad".

Evaluator C:

"Non-conformances consequence of this type is ok, but our priority is the VOC non-conformances, i.e. voice of customer. Customers - the user, like the R&D our customer is the production. Hence, it is very critical where the consequence is reflected in costs. Then followed by quality target, i.e. specification from engineering samples to the production, based on our internal view and customer requirements and VOC. R&D will try to comply with production requirements or an agreement VOC. Then there's the cost of prototype to consider.

It's tangible, covers main aspects, relevant in analysis and problem solving".

Evaluator D:

"This is pretty much the same. When there is a NG, then we give it a rank, A, B or C; A is very major, for example no function, if have we do not have the countermeasure, we do not run production – should and must be solved earlier. B is less which has partial countermeasure and C improve with care, if carrying out can be negotiated. We allocate 95% allowable for product to go, but if one problem like function is not working - it means product still can go. This is no

meaning! That's the problem with percentiles. May be later we have to change to this".

Evaluator E:

"This is a good and practical technique, it's suitable. The drawback with the major/minor classification is that it depends on individual judgement and experience. He determines what is major or minor. It's good if this can be a validation standard for people to follow".

Evaluator F:

"Our classification is based on type class 1, for example safety, then decide the status, for example the non-conformance is 'no go' means nothing can be done. Then type class 2 not safety – the status, for example is the non-conformances severe? Can it be contained or not? The type class 3 is for information only, i.e. it fails but so what?

Yours is the other way around, i.e. classifying according to the technical aspect, and this table is applicable to engineers but not from the business aspect. It looks at the characteristics of the non-conformances on a product".

Q C7. Overall Methodology

In your opinion, after evaluating the new approaches in product validation process, do you suggest the approach is

	Yes	No	Not Sure	Don't Know	Please elaborate
i coherent?					
ii. practical?					
iii. recommended?					

Evaluators' response:

Evaluator	*A*	*B*	*C*	*D*	*E*	*F*
i. coherent?	Yes	Yes	Yes	Yes	Yes	Yes
ii. practical?	No	Yes	Yes	Yes	Yes	Yes
iii. recommended?	Yes	Yes	Yes	Yes	Yes	Yes

3 items/18 responses (17 = Yes, 1 = No)

Evaluators' comments:

Evaluator A:

"I would say it is relevant, workable, but too theoretical, and not sure it's practical – have to test it, especially on the NoCoS, non-conformances people use it and see from the numbers they can grasp the problem, it should be ok. I also recommend trial-run, or pre-production."

Evaluator B:

"I think generally it's ok, but from which point of view? Academic or industrial – it depends. I see you try to integrate both. I also recommend to emphasise human factors, because most of the time the non-conformances are from them."

Evaluator C:

"In my opinion, they are very much relevant, sensible, and practical. Actually this non-conformance is a very much and highly recommended approach. I even distributed to these to my subordinates to go through this idea. Actually we hate it, but on the contrary we should love non-conformance at the very early stage.

R&D should think of the potential problems from now on, not at pre-production".

Evaluator D:

"I'd say it is 95% applicable in what we are doing now with a bit of variation on equipment, design, development and processes fine-tuned depending on products. This is good for us to have initial inspection of our design for certain confidence levels and references before proceeding to the next step. Since the quantity is small, it does not reflect the production condition, for example in the 1000^{th} set, or after some time, before we detect problems".

Evaluator E:

"It is suitable; I suggest it to be a standard to be applied in validation".

Evaluator F:

"Ok, but I think validation should consider time factor for changes to requirements, environment, for example international market requirements. The validation should be flexible to accommodate to the changes. Also anticipate and provide room for future or additional need which may not be important at that time."

APPENDIX D: PHASE 2 EVALUATION

D1. Schedule of Questions to Evaluate Validation Process

(to be read with APPENDIX B – Product Validation Workbook)

EXPERT PANEL INTERVIEW

SCHEDULE OF QUESTIONS

(Phase 2)

GENERAL INSTRUCTIONS AND INTERVIEWER SELF-INTRODUCTION

First of all, I would like to thank you, Mr/Mrs/Ms. _____, for allowing me to carry out this interview, which is also known as an **expert panel interview**. The purpose of this interview is quite self-explanatory, that is to get an **expert evaluation,** from a person like you, on **specific aspects** related to my research, as well as the industry as a whole. Your answers are very important to the accuracy of the research, and I can assure you that they will be treated and kept as **strictly confidential**.

Before we begin, Mr._____, allow me to introduce myself. My name is Roslan Jamaludin. I am currently pursuing a 3-year PhD research programme at the Wolfson School of Mechanical & Manufacturing Engineering, Loughborough University, UK, since December 2003. I am a Product Designer by qualification, and teaching Production Technology in Universiti Utara Malaysia. My research focuses on ***Identifying and Controlling Product Non-conformances in Pre-production.***

For effective discussion, **this interview will be divided into 4 parts,** so that the subjects can be addressed appropriately.

PART A – Expert and Company Profile
PART B - Appropriateness of Non-Conformances Concepts
PART C - Practicability of New Approaches
PART D - Appropriateness of the Workbook

(Note: The questions below require your PERCEPTION, CRITICISM, COMMENT AND SUGGESTION).

PART A – Expert and company profile

Q A1: For the record, could you please state your **personal details**;

- What is your **designation**?
- How many years and months in your present **position**?
- How many **years' experience** with this company?

Q A2: Could you please give a brief **description of your company's**

- business **profile** and **products**?
- where is the **head office** location?

Q A3: What is company current **business philosophy** on product and quality assurance?

End of PART A

PART B - Appropriateness of new approaches in pre-production

(Note to evaluator: to evaluate, please refer to validation workbook)

Q B1: Do you think identification of non-conformances based on product characteristics described in Section 2.1 is appropriate in product validation?

Q B2: Do you think the manifestation of non-conformances based on the PNC, as described in Section 2.3, is valid?

Q B3: Do you think the NoCoS methodology, as described in Section 2.4, is appropriate in controlling non-conformances?

End of PART B

PART C - Practicability of new approaches in product validation

Q C1: Do you think the product **validation model**, as described in Section 1.5, is appropriate in pre-production?

Q C2: Do you think the **validation process steps,** as described in Section 1.6, are appropriate in pre-production?

Q C3: Do you think that the **general rules,** as described in Section 2.1, are appropriate in product validation?

Q C4: Do you think the following **steps** are appropriate?

- Step 1 - INITIATION, as described in Section 2.2
- Step 2 - DETECTION, as described in Section 2.3
- Step 3 - ANALYSIS, as described in Section 2.4
- Step 4 - RECTIFICATION, as described in Section 2.5
- Step 5 - VERIFICATION, as described in Section 2.6

Q C5: Overall, what do you think of the procedure?

End of PART C

PART D. Appropriateness of the validation workbook

Q D1: What is your opinion on the **format** or **presentation?**

Q D2: Do you think the **annexes** and **examples** given in pages 46 to 58 are appropriate?

Q D3: What is your opinion on the **overall** workbook content?

End of PART D

Thank you, Mr._____ for your time and willingness to participate in this Expert Interview. Your opinion and views will definitely be used and referred to throughout this research. With your permission, I would be grateful if you would be willing to be interviewed again, if necessary, at any time during the research.

Thank you, and that will be the end of the interview.

APPENDIX D : PHASE 2 EVALUATION

D2. Phase 2 Evaluation: Interviews Transcription

TRANSCRIPTION

(Phase 2)

PART B - Appropriateness of new approaches in pre-production

Q B1: Do you think identification of non-conformances based on product characteristics described in Section 2.1 is appropriate in product validation?

Evaluator X:

"I think in validating a product, this is the essence of what we should do. We should be detecting what is not following our spec. In my experience, normally we use a checklist. However, it doesn't really focus on the non- conformances."

Evaluator Y:

"In detecting non- conformances, it should begin in the design stage, not in pre-production. The pre-production, in this case, may prevent the non-conformances escaping into the production."

Evaluator Z:

"My view is we should first capture the common problems that might occur in the market during validation. That should be the priority."

(continued)

PART B *(continued)*

Q B2: Do you think the manifestation of non-conformances based on the PNC, as described in Section 2.3, is valid?

Evaluator X:

"This has accurately described what might go wrong in pre-production from the production aspects (parts and process). This also described the design aspect that causes the non-conformances. This happened in the pre-production because the product is still under development, i.e. not fully complete yet, and it could affect the validation."

Evaluator Y:

"The list (Table 2.3) should be in order of priority, e.g. the most important is the Work Instruction. So it's under the Information non-conformances. Those listed are actually happening in the production."

Evaluator Z:

"Our checklist will first look at Safety, as shown in the example; the list shows it's under Information Error. We will normally do the Safety inspection first. This example is also a common problem."

(continued)

PART B (continued)

Q B3: Do you think the NoCoS methodology, as described in Section 2.4, is appropriate in controlling non-conformances?

Evaluator X:

"Compared to our classification of problems, this is more complicated. We classify only into 3 – A (most critical), B (less critical) and C (minor). When found a Class A problems should be resolved immediately, e.g. pertaining to safety, functionality and anything critical to customer, whilst Class C should only be improved when possible. However, final judgement lies with the QA."

Evaluator Y:

"On our side, we need to clarify everything before production. The status of the model is confirmed in Confirmation Meeting, e.g. the design, safety, etc. The NoCoS is appropriate for validation."

Evaluator Z:

"We have our own way to analyse, but this may be OK."

End of PART B

PART C - Practicability of new approaches in product validation

Q C1: Do you think the product validation model, as described in Section 1.5, is appropriate in pre-production?

Evaluator X:

"To me, very much agree to this model. When we validate a product, we need relevant information on the production, the production will control the process and parts/components control by incoming quality control department. This model is similar to what we are doing, I cannot add anything more."

Evaluator Y:

"As to the process, what we did is according to the check sheet, e.g. information from the designer like the standards, specification, bills of material and cost-down information. So, no problem with this model."

Evaluator Z:

"I think this is an appropriate model, as we follow-up the design and the production."

(continued)

PART C (*continued*)

Q C2: Do you think the validation process steps, as described in Section 1.6, are appropriate in pre-production?

Evaluator X:

"Basically the steps are logical. However, these steps focus more on finding non-compliances rather then compliances. What would be the differences in finding conformances, would it be the same or would there be any special items? Because I think it's automatic when we do one thing, the other one will also be done automatically. I cannot think of any differences in term of steps taken or if you say concentrating on finding compliances or concentrating on non-compliances. If I want to find compliances, I'll go through item by item systematically. This one is ok, this one is not ok, and so on". *(Evaluator's comments too early, before reading and understanding the whole validation process).* Some problems are not in the checklist, so what are the different items if you want to find the non-compliances? I don't have the answer to this. It's good to have a different steps or checklist rather the general one."

"Further steps will describe the specific way to capture only the non-conformances" (Interviewer).

Evaluator Y:

"I see you have the steps of preparation and inspection. There should be the step to inspect the fitting/assembly to detect non-conformances, e.g. the design set will be dismantled, and the Engineering team have to re-assemble. Need to check until there is no problem at all. If there are problems, then it goes back to normal inspection. The rechecking is in the steps, but the re-assembly of the design set is not mentioned in the steps."

Evaluator Z:

"To me, the steps are appropriate."

(continued)

PART C (continued)

Q C3: Do you think that the general rules, as described in Section 2.1, are appropriate in product validation?

Evaluator X:

"We do not do 100% inspection on all products; it depends on a case-by-case situation. If there are a lot of problems, the inspection will be done on a longer period. If there is no problem, normally only the first 1k will be inspected. This is a good rule, but it takes more manpower and longer period."

Evaluator Y:

"We did a 100% inspection. When we detect major problems, we inform designers to get immediate feedback and prevent it happening in the production. The steps (rules) are important."

Evaluator Z:

"We actually do the 100% inspection; say the samples of 30 sets, all the samples are inspected in pre-production. We will detect the mechanical, electrical and mecha-tronic, and feedback to the relevant functions, then follow-up with the countermeasures. The preventive measures are referred to on the preventive action sheet i.e. based on the past experiences. New preventive measures will be added into the sheet."

(continued)

PART C (continued)

Q C4: Do you think the particular steps below are appropriate?

- Step 1 - INITIATION, as described in Section 2.2
- Step 2 - DETECTION, as described in Section 2.3
- Step 3 - ANALYSIS, as described in Section 2.4
- Step 4 - RECTIFICATION, as described in Section 2.5
- Step 5 - VERIFICATION, as described in Section 2.6

Step 1 - INITIATION, as described in Section 2.2

Evaluator X:

"The organising, preparing and familiarising the new product are all necessary steps to start the validation. I think these are appropriate."

Evaluator Y:

"Step 1 is necessary to be conducted, e.g. preparation based on the product planning information; sharing of new product information among validation teams so that everybody has the same and common understanding; organise team i.e. delegate jobs and who in-charge. So this is OK."

Evaluator Z:

"This step is very important; we need to know what the new model is, so that we can study any relevant material, if it's a similar product, recall and attack the similar problems first. If there are new features, we will have to think how to inspect them."

(continued)

PART C (continued)

Step 2 - DETECTION, as described in Section 2.3

Evaluator X:

"I think it's quite clear there's not much to say, the step to capture problems and what you do with them only up to this step. Definitely this is a necessary step, and I don't have anything to add."

Evaluator Y:

"It is clear-cut in pre-production to detect non-conformances in samples and log result as proof or evidence."

Evaluator Z:

"Similarly, and we capture the problems, rank them e.g. A, B or C. If it's A, that needs rapid solution; if C, not so urgent. Our inspection is based on customer perspective, i.e. the features and functionality."

Step 3 - ANALYSIS, as described in Section 2.4

Evaluator X:

"If something happens and having no idea of the root causes, it's very difficult to classify. The only way is to classify whether it is serious or not. Others like button jammed are easier to classify. The classification is based on seriousness of the problem which directly affects the overall subject, when not knowing the causes. After classifying the problems then we look for the root cause. If not, we might make the problem worse if we don't understand what causes it. So finding the cause is the priority before starting any solving method.

One more thing, because we have our schedule and dateline to meet, so what we normally do, though finding the root cause is vital before we can do major design revision, there are normally two kinds of solutions to each problem – temporary and permanent. Temporary is doing whatever we can to settle the problem to run the production well in the short-term, at the same time without

incurring high cost. At the same time, do analysis to find the root cause and find appropriate counter measures."

Evaluator Y:

"In pre-production, step 3 is important, e.g. the post mortem, we have to find the evidence of the cause to a problem. If the reject item is serious, we do temporary action or permanent countermeasure. Temporary countermeasure is needed (after agreed by all members) to meet early schedule shipment. We classify the problem as go or no-go (line is totally cannot run), i.e. from production and customer point of view, as mentioned earlier. If unknown problem occurs, we ask the R&D; for known problem, we take immediate action to run the production. We will ask the R&D (feedback) for the temporary counter measure. If we modify ourselves, the problem might get more serious."

Evaluator Z:

"We hope to find problems earlier in the pre-production, everybody hoping the pre-production team find as many problems as possible. The QA will check the less technical aspects; the technical ones are checked by the engineering people. The constraint in pre-production is meeting the schedule from the pre-production to mass production when the checking is too short and the problem is serious."

Step 4 - RECTIFICATION, as described in Section 2.5

Evaluator X:

"It is connected with the analysis. This is the solution step. In addition, the temporary and permanent solutions are required. For normal problems, the solution can be implemented right away, whilst new problems need to implement and test the solution by trial-run, if not, the problem might become more serious."

Evaluator Y:

"I agree with the R1, it is dangerous when solutions are implemented without testing first, especially in the production. This is a wrong approach, it bypasses the QA. We need all modification to get QA's test and cost qualification."

Evaluator Z:

"Whatever modification and counter-measure, we will retest. If the counter-measure and testing cannot be done in time for mass production, we do recovery to the lowest specification acceptable by the customer. That will be for a conditional and limited batch whilst allowing design to study further."

Step 5 - VERIFICATION, as described in Section 2.6

Evaluator X:

"To verify is also to assure the validation is positive. As an additional step, disseminating the result of validation, especially pertaining to a new or major problem and solution throughout other assembly plants around the world, is significant. For example, recently on a safety problem on one of our products built in Indonesia, we were acknowledged rapidly on this issue. This will be a lesson learnt for the next model."

Evaluator Y:

"Logging the results of the previous step is needed; other departments which have access to the report must implement or take appropriate action relevant to each department."

Evaluator Z:

"We used to refer to the previous model when verifying to compare. In the meeting, all the departments will sign the verification certification form, which is led by the Engineering Department."

(continue)

PART C (continued)

Q C5: Overall, what do you think of the procedure?

Evaluator X:

"This procedure as mentioned is limited in scope, otherwise there are other aspects to consider, which are out of the scope. However, what it covers does have very good coverage and quite detailed. So I think, in general, the workbook is appropriate based on the scope. Other than capturing and measuring NC, it does not go in detail on how to do preventive action on new problems because different products having different problems. It did not describe on actual product."

Evaluator Y:

"This workbook can be used in the production as guidance because it is appropriate, as it describes step by step, and the examples/annexes are happening and relevant. It is good as training material to new staff." (*Not answering the question*).

Evaluator Z:

"This workbook is required, especially for new staff. I understand the procedure quite comprehensively, since they are not too detailed. There are other aspects to include, e.g. testing; however, in general, it can be applied to many products and to other companies too since the procedures are similar." (*Not answering the question*).

End of PART C

PART D. Appropriateness of the validation workbook

Q D1: What is your opinion on the **format** or **presentation?**

Evaluator X:

"It is very clear. The steps can be followed quite easily. In general, the layout is simple and straight to the point, easy to understand, but not sure of implementable as it requires a little bit more detail."

Evaluator Y:

"The examples are very relevant. The prevention strategy is very practical. Since we have a lot of similar models, we suggest designers adopt these, hence the procedure is easy to follow by the production."

Evaluator Z:

"The procedure is easy to understand even by those not well versed in English. The steps are clear and complete with examples."

(continued)

PART D (continued)

Q D2: Do you think the **annexes** and **examples** given on pages 46 to 58 are appropriate?

See Q D1

Q D3: What is your opinion on the **overall** workbook content?

Evaluator X:

"The workbook is relevant, comprehensive, and definitely coherent. It's very practical, and I recommend it especially to someone not familiar with the production and the problems with model development. It's very good for a background understanding."

Evaluator Y:

"It is good as a training material which describes the standard format, step-by-step, the process, and what action to take. It is practical, appropriate and complete. We suggest using this as a reference for new members."

Evaluator Z:

"I agree very much with Y; particularly the annexes are appropriate."

(continued)

PART D (continued)

Q D4: Do you have any suggestions to improve the workbook?

Evaluator X:

"Some suggestions. Add one example of an actual walkthrough step-by-step implementation besides the purpose, procedure and activity, for better comprehension. As mentioned earlier, before the verification step, testing the countermeasure is necessary before implementation and confirmation."

Evaluator Y:

"I agree with R1, the additional example may complete the workbook."

Evaluator Z:

"Since testing is not included, I have nothing to add."

End of PART D